
RISK-BASED INSPECTION OF MEAT AND POULTRY PRODUCTS
FINAL REPORT ON THE RBI STAKEHOLDER INPUT PROCESS

Prepared by

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I. BACKGROUND AND METHODOLOGY

A. General Background on the RBI Stakeholder Input Process

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture is the public health agency in the United States responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. In 2004 FSIS launched an initiative to make its meat and poultry inspection system more risk-based in order to better protect the consuming public. This risk-based inspection initiative (RBI Initiative) is the next step in FSIS's plan to modernize the U.S. food-safety inspection system. FSIS introduced and implemented a series of initiatives in the mid-1990s that established the foundation for the RBI initiative. In 1996, the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Final Rule clarified the respective food safety roles and responsibilities of industry and FSIS in meat and poultry plants. In 1997, FSIS initiated the HACCP-Based Inspection Models Project (HIMP), which focuses more control for food safety and other consumer protection activities on individual establishments, with the Agency verifying the success of the establishment's efforts. In 2005, FSIS initiated a risk-based pathogen control program for *Listeria monocytogenes* (*Lm*), and in February 2006 an 11-step risk-based strategy to reduce *Salmonella* in raw meat and poultry products.

When the Agency launched the RBI Initiative, it determined that obtaining stakeholder input would be a major aspect to any risk-based inspection program's effectiveness and success. During development and implementation of the programs listed above, FSIS interacted with its many stakeholders through a variety of channels and venues, to discuss and solicit feedback about the programs under its authority. Included among these venues were the National Advisory Committee on Meat and Poultry Inspection (NACMPI); the National Advisory Committee on Microbial Criteria for Foods (NACMCF); joint and separate consulting sessions with consumer and industry representatives; technical meetings and outreach to small and very small plants; and information exchanges with FSIS employees.

At the recommendation of the NACMPI at its November 2005 meeting, FSIS decided to work with a third party to assist with reaching out to, and gaining input from, its stakeholders. FSIS selected RESOLVE who began facilitating the RBI Stakeholder Input Process in May 2006. RESOLVE is a non-profit organization specializing in facilitating and building multi-stakeholder agreements on complex natural resource, energy, and public health policy issues. Founded in 1977, RESOLVE has offices in Washington, DC and Portland, OR. For almost 30 years, RESOLVE has helped diverse interests engage in dialogue, problem solving, and collaborative decision making to develop improved solutions to public policy issues. The RESOLVE team who organized and facilitated the RBI Stakeholder Input Process included Senior Mediators Abby Dilley, Paul De Morgan, and Kathy Grant, and Facilitator Brad Spangler.

FSIS asked RESOLVE to conduct the following tasks (See Appendix A for full Statement of Work):

- Task 1: Plan and Conduct a Public Meeting on RBI;
- Task 2: Establish an Opportunity for Stakeholder Input Electronically;
- Task 3: Synthesize Stakeholder Input and Report Important Findings to FSIS; and
- Task 4: FSIS Interaction, Progress Reports, and Key Deliverables (Meet regularly with FSIS, submit monthly progress reports, and report key findings and recommendations at prescribed milestones).

B. Overview of Methodology for Collecting Stakeholder Input

RESOLVE facilitated the RBI Stakeholder Input Process between May and November 2006, carrying out a variety of activities associated with the tasks listed above and interacting with a broad cross-section of stakeholders interested in and affected by meat and poultry inspection. RESOLVE reached out to and/or spoke with representatives of the following stakeholder groups: FSIS employees; consumer groups; business owners/operators; industry associations; employees of slaughter and processing plants; public health groups; other federal agencies, state and local inspection agencies; and academic experts in food safety, risk analysis, and data systems.

RESOLVE gathered stakeholder input, primarily on the two components of RBI, but also on FSIS's very early ideas about implementation of RBI and other aspects relevant to the RBI Initiative. Three specific mechanisms were created to provide opportunities for stakeholder input: 1) Organized discussions with individuals and groups of stakeholders representing the range of stakeholders; 2) A two-day Public Workshop held October 10-11, 2006 in the Washington, D.C. area; and 3) Electronic input submitted through the FSIS website. Comments, questions, concerns, and suggestions from all of these mechanisms were reviewed, organized, summarized and are presented in this report.

To capture and present their preliminary thinking to stakeholders and prompt specific input, FSIS developed concept papers on the two major components of the envisioned RBI system. The first paper was on *product inherent risk* (PIR) – a measure of the inherent risk posed to public health by each type of processed meat or poultry product. The other paper was on *establishment risk control* (ERC) – a measure of the amount of actual risk control achieved by each establishment. The papers were distributed prior to organized discussions with stakeholders and posted on FSIS's website.

RESOLVE first began its facilitation efforts by developing a knowledge base about key concepts, inspection activities, and events leading up to FSIS's RBI Initiative. RESOLVE staff reviewed relevant background materials, attended the May 2006 meeting of the NACMPI including the RBI Subcommittee session, and met with the FSIS RBI Steering Committee. To ground their understanding of current inspection processes, RESOLVE staff visited a variety of meat and poultry slaughter and processing establishments. (See Appendix B for details on the activities RESOLVE carried out to develop a knowledge base for facilitating the stakeholder input process.)

RESOLVE next contacted approximately forty-five stakeholders for in-depth discussions. The discussions focused on gathering perspectives on the overall concept of risk-based inspection; the two components of RBI as described by FSIS in the papers mentioned above; and ideas about the design of the Stakeholder Input Process, including the Public Workshop. The information gathered through the discussions with stakeholders, along with consultation with the NACMPI Subcommittee on RBI, informed RESOLVE's suggestions to FSIS on the design of and planning for the two-day RBI Public Workshop, as well as the substantive content of the Agency's presentations. RESOLVE facilitated the Public Workshop and compiled all stakeholder input generated on-site, as well as comments submitted by web-based (i.e. remote) participants. Immediately following the Public Workshop, RESOLVE staff attended the October 12-13, 2006 NACMPI meeting, at which FSIS staff made another presentation on the Agency's initial thinking on implementation of RBI and gathered additional feedback. Following these meetings and up to the end of October, FSIS made available to RESOLVE information submitted via the RBI electronic input mechanism and the *Federal Register*. RESOLVE compiled, reviewed, organized, and wrote this report summarizing the collective stakeholder input. (For complete details about

RESOLVE's methodology for the Stakeholder Input Process, please see Appendix C.)

C. Summarization of Comments and Development of the Report

This report summarizes the range of stakeholder input about RBI gathered by RESOLVE in the May to November 2006 Stakeholder Input Process. Sections II - V of the report contain a compilation of all of the input gathered throughout the process. Section VI of the report suggests opportunities and next steps for building on work to date, including potential for additional constructive stakeholder input in further developing risk-based inspection for meat and poultry processing.

In reading the compilation of stakeholder input, it is important to keep in mind that it reflects information from FSIS and opinions from stakeholders that evolved as the Stakeholder Input Process progressed. As FSIS's thinking about the components of an RBI system continued to evolve and take shape, informed by the input received from stakeholders, so too did stakeholders' reaction to and opinions about both the specific components and FSIS's approach to RBI. As was their aim in reaching out to stakeholders prior to finalizing the design and implementation of a more robust RBI system, the Agency received instructive and constructive feedback and suggestions about the design, implementation, and evaluation of RBI. Early input from stakeholders influenced the ongoing Stakeholder Input Process and FSIS's thinking about the design and implementation of RBI. For example, early formal discussions with stakeholders about the two concepts papers helped shape the Public Workshop agenda and the presentations on PIR, ERC, and Implementation. The fluidity and interactivity of FSIS's work and the Stakeholder Input Process have helped address some of the questions and concerns voiced by stakeholders early in the information-gathering phase.

The most challenging aspect of this ongoing evolution of the Stakeholder Input Process is its impact on developing a comprehensive analysis of stakeholder input on all aspects of RBI and a more robust RBI system. At different points in the process, different stakeholders were responding to different information and different questions about an RBI system. As a result, this report, while summarizing what we learned from stakeholders throughout the Stakeholder Input Process, does not represent a comprehensive summary of all stakeholder opinions on each of the components of RBI presented by FSIS.

To illustrate this point, during early telephone discussions, stakeholders responded to general questions about RBI, PIR, and ERC based on FSIS's thinking at that time, but without information about the context of FSIS's goals and objectives or details about the expert elicitation on inherent risk¹. At the Public Workshop, stakeholders made their comments in the light of new information about FSIS's vision and implementation concepts, more detailed presentations on PIR and ERC, including more information on the expert elicitation, as well as more specific questions about these concepts. Stakeholder opinion continues to evolve as evidenced by some of the electronic comments submitted subsequent to the Public Workshop. However, even the electronic stakeholder comments are devoted to particular aspects of RBI that vary according to the specific interests of the different stakeholders. Those comments therefore also lack the consistency necessary for a comprehensive summary and comparison of views since each comment focused on different, but not all, aspects of an RBI system.

¹ Risks of Meat and Poultry Products: An Expert Elicitation

II. OVERARCHING COMMENTS AND THEMES FROM STAKEHOLDERS

In the course of holding formal discussions with stakeholders, facilitating the Public Workshop, and reviewing additional public comments, a series of overarching comments emerged that, while relevant to the two papers and implementation, warrant additional and separate consideration.

A. General Reactions to the Risk-based Inspection Concept

The idea of utilizing risk as a means to best deploy inspection resources received a broad range of reactions from stakeholders. In their comments, stakeholders sometimes made a distinction between the general concept of using risk to determine inspection effort and the specifics of the RBI system FSIS has been developing. Most of the stakeholders from all interest groups support the general concept of risk-based inspection, which they interpreted as using a measure of risk to better allocate inspection effort in order to more effectively protect public health. Stakeholders suggested that RBI is a logical step in allocating resources to further improve food safety and decrease public health hazards. At the same time they emphasize that RBI must be based on criteria that adequately and accurately reflect risk. Stakeholders also express general acceptance of the concept of applying agency resources to those establishments with the highest likelihood of causing human illness, particularly if risk control at those establishments is currently below industry practices and regulatory requirements.

Support is broad for the type of program that enables FSIS to improve resource allocations and mitigate the impact of food-borne pathogens. However, some stakeholders have serious concerns about implementation of RBI as a program if the FSIS-proposed system does not address some fundamental issues. These issues include the impacts on inspector jobs, presence and authority of FSIS personnel within establishments, additional requirements for establishments, whether and how the RBI system will, in fact, better protect public health, and whether the proposed system will be able to verify improved public health protection. How and where the RBI system shifts resources is of acute interest to all stakeholders for both similar and unique reasons.

Some stakeholders are cautiously optimistic about both the concept of using risk to determine inspection effort and their preliminary understanding of what FSIS is proposing. Their caution stems from many factors, including: a) appreciation for the complexity and challenge of generating clear and robust models for determining risk; b) gathering and managing the data necessary to support those models; and c) adjusting resources with the confidence that the results will improve food safety and better protect public health. Their caution also stems from very strong personal interests – associated with their professions, their establishments, their reputations, and their personal and family health – concerning the impacts of implementing any RBI model.

Several stakeholders closely link their view of the developing RBI system with the process being used to develop it. These stakeholders have suggested that soliciting input from all interested parties, although controversial at times, is essential for establishing a more robust and acceptable RBI program. The high stakes that the diverse interested parties associate with an enhanced meat and poultry inspection program, in part, drive these views. Many of these stakeholders also believe that a broader understanding of FSIS's thinking and decision making for developing RBI, and a creative and collaborative process for injecting different points of view into that process, will ultimately result in the establishment of a stronger and more broadly supported program.

Almost every stakeholder indicated a need to understand how the two independent measures of risk – one for product and process and the other for establishment controls – will be brought together to make decisions about where and how to allocate inspection resources. Without this explanation, stakeholders found it challenging to comment on aspects of RBI and to form opinions about the Agency’s proposals for implementing it. Stakeholders also expressed concern about the simplistic nature of the overall algorithm and stressed the importance of seeking advice from mathematicians and modeling experts to assess whether the formulas FSIS are using are oversimplifying the analysis and therefore subject to error.

Some stakeholders have articulated elements they see as critical to successful development and implementation of an effective RBI system. One group suggested the following: be transparent; be consistent with governing law; ensure all processing establishments are subject to at least some minimum level of daily inspection (as well as subject to all related requirements); and clearly enhance public health as demonstrated through objective assessments.

Some stakeholders strongly argued that the PBIS is not being implemented correctly and that proposed changes will, in fact, weaken food safety. They stated as an example that although PBIS requires an inspector to visit every plant at least once every shift, that, in fact, this requirement is not being met. Therefore, suggesting that FSIS’s efforts are being developed and evaluated based on the PBIS operating at maximum efficiency is erroneous and, possibly worse, from their perspective, may be used to argue for even less inspectors or inspector presence (physically and authoritatively). A few stakeholders have indicated opposition to any efforts by FSIS to implement RBI at this time given their assumptions about FSIS objectives associated with the RBI Initiative.

B. Goals and Objectives of RBI

1. A Public Health Approach

Several stakeholders (and particularly representatives of consumer groups and academia) raised significant concerns about the stated goal of risk-based inspection – preventing food-borne illness – and the failure to incorporate the essentials of a public health approach into the risk-based inspection process in order to meet that goal. One stakeholder described the “public health approach” in this way: first, identify the pathogens that cause human disease; then identify where these pathogens enter the food supply chain; and then, based on that information, target the entry points to prevent human disease. For these stakeholders, the algorithm as proposed by FSIS does not address the extent to which a product is associated with a food-borne illness outbreak.

To address this concern, one consumer group suggested that FSIS step back from the approach they are proposing, and refer back to the two reports written by committees of the Institutes of Medicine (IOM) and the National Research Council (NRC) to create a new plan that is based on the principles, objectives, and elements spelled out in these reports: *Ensuring Safe Food from Production to Consumption* (IOM/NRC 1998) and *Scientific Criteria to Ensure Safe Food* (IOM/NRC 2003). This group noted that these reports, which include basic elements integral to the design of a risk-based food safety system, were commissioned by Congress and paid for by the Agency.

2. Legal Authority

Some stakeholders from diverse interests explored the question of whether FSIS has the authority to set regulatory standards or in some cases even to enforce science-based standards. They believe that FSIS does not have such authority because of the Supreme Beef court case, which overturned the performance standards set for *Salmonella*. If this analysis is correct, and the Agency cannot set standards or deploy inspectors to ensure compliance with these standards, the inspection system (in the view of these stakeholders) will be a step removed from a public health outcome. In this case, they suggest, “The system will then be based on the mistaken premise of traditional FSIS inspection: FSIS should not deploy resources to stand in the line; they should use resources to provide incentives (i.e. enforcement tools) for companies to meet established performance standards.”

One stakeholder suggested that FSIS is politically constrained from seeking legislation to solve this problem. While some stakeholders understand that these limits are due to statutory and legal history and acknowledge that the approach FSIS is taking is attempting to make improvements in spite of these limitations, other stakeholders believe that FSIS should do more to change this history and precedence and, further, that if they do not, the approach is fundamentally and fatally flawed. Some stakeholders – who believe this authority is essential to a successful RBI program – indicated they could not support current FSIS RBI efforts, though they would be willing to support new efforts to secure appropriate legal authority.

Other stakeholders, particularly from industry, stated that FSIS does not have the legal authority to establish and enforce performance standards nor should they. They further commented that authority to set and meet standards and make changes appropriately rests with establishments and FSIS’s role should continue to be the evaluation of establishments’ efforts to control risk.

It was noted that the FSIS papers suggest that in the new system, resources would be allocated so some companies have inspection that is more intensive and some have less than they currently experience. Some stakeholders suggested that while it is unlikely any plant would complain about less intensive inspection, it is unrealistic to assume that some plants, subjected to increased levels of inspection, will not challenge the legality of this system. FSIS, they commented, will need to consider how to respond in these cases. If the Agency’s authority to effectively implement the RBI system is not upheld or affirmed, it will likely fail.

3. Focus on the Whole Food Chain

A conundrum was raised by some stakeholders, including industry, academia, and consumers, regarding the current focus of the proposed RBI system. They suggested that although FSIS is focused on using RBI to allocate resources in meat and poultry processing establishments, it should consider longer term plans to apply RBI over the broader food supply chain continuum from farm to table. In their view, if the goal is reducing food-borne illnesses caused by meat and poultry products, an RBI approach may pay greater dividends if the focus is upstream from processing establishments or further downstream at institutions, retail establishments, and restaurants. As they see it, only by examining and addressing risks posed by food-borne pathogens along the entire food supply chain will resources ultimately be directed where they are most needed to optimize risk reduction and enhance public health. Agency resources might not be best prioritized under the

current approach, which focuses only on meat and poultry processing establishments and not the whole “farm to table” chain.

C. Use of Data and the Infrastructure in Place to Consider Data

1. Do Current Data Support the Move to RBI?

Some stakeholders – from all sectors – indicated concerns with both the rationale and the data being used by FSIS to support moving to a “more robust” RBI system. For example, a couple of stakeholders highlighted FSIS’s statements that the current “risk-based” programs have led to reductions in pathogen rates in regulatory sampling. These stakeholders stated that other USDA officials have questioned the regulatory sampling assumptions, and that the CDC has indicated that progress against illness has dropped. As such, they do not believe FSIS has sufficient evidence to justify major changes in the inspection program.

2. Cart before the Horse?

Several stakeholders from all interest groups shared their concern that FSIS is establishing an elaborate scoring system without, in their view, having clear data (or a way to gather it) to show the program will actually accomplish the goals of decreasing public health risk and effectively allocating resources.

Many stakeholders note that defining the criteria used to assess and measure risks is a major challenge related to this type of inspection program. These stakeholders all believe that these criteria must be linked to the public health consequence or impact, preferably through use of scientific data. However, these types of linkages are often difficult to substantiate because of limitations in food attribution data, insufficient or non-existent data-sharing protocols, inadequate knowledge regarding the extent to which inspection issues relate to food safety, and the tremendous variety among the federally-inspected plants in terms of size, production volume, types of products, formulations, technologies used to produce meat and poultry products, as well as technologies used to reduced microbiological and other food safety hazards, etc.

As a result, in the view of these stakeholders FSIS should focus first on obtaining the data necessary to assign risk, rather than on building the nuts and bolts of the system. They contend that once the system is built, it will be more difficult to adapt and modify if the data require it. It was also noted that in order to get the necessary data, FSIS would have to work with industry more creatively and effectively than it has in the past. Not surprisingly, there are different points of view among stakeholders as to what data and information are most important to collect, use to determine risk, and assess whether the RBI system is successful; there are also differing views on how to best obtain the desired data.

Most stakeholders emphasized that developing an accurate picture of risk is critical for targeting and deploying resources most effectively to address the risk, as well as for signaling expectations to those involved in the meat and poultry processing (and arguably the whole farm to table) system, and for conveying appropriate information to the public. While some stakeholders suggest an inaccurate picture could create too great a concern about food safety and inappropriately suggest greater risks associated with particular types of meat and poultry products or establishments, others are very

concerned that an inaccurate public perception may endanger the public's health, particularly those most at risk for food-borne illness.

3. Attribution Data

Significant time was spent at the Public Workshop (and in other conversations) regarding the issue of attribution data and how important it is to the success of a risk-based inspection system. Many stakeholders, including academic, consumer, and industry representatives, encouraged FSIS to examine attribution data that connects food-borne illnesses from specific pathogens to particular products. As they see it, using attribution data, especially as it is more quantitative in nature, will make RBI more effective, accurate, and efficient.

As noted above, this approach to food safety requires certain tools and data that currently do not exist or at least are not collected or accessed effectively. Stakeholders offered the following suggestions for other methods FSIS can review and consider to estimate food attribution percentages: an expert elicitation; use of outbreak data in which illnesses are traced back to their originating food; and a risk assessment based on food contamination data, food consumption data, and algorithms for estimating resulting illnesses.

The issue of attribution data came up specifically with respect to the expert elicitation used to rank categories of meat and poultry products. It appeared to many who read the papers that FSIS did not develop new data to help define inherent risk and made no apparent effort to integrate existing food attribution data into its model. As discussed in more detail in Section III (PIR) of this report, stakeholders have urged FSIS to conduct another expert elicitation and include attribution data in the process.

Stakeholders also emphasized the need to continually update attribution data, particularly because there are always new and emerging food-borne pathogens, as well as various strains of existing ones. While a product may not have a significant public health risk at one time, in a few years a problem may arise.

4. Salmonella Testing Program

Some consumer groups and other stakeholders emphasized that the FSIS *Salmonella* testing program needs to be addressed prior to implementation of the RBI system. They specifically cite the September 2006 audit report by the USDA's Office of Inspector General, *Review of Pathogen Reduction Enforcement Program Sampling Procedures*, which had found that some controls need strengthening within the testing program and that some establishments were being excluded from testing because of ineffective controls. Others noted the minimum "set" (currently 51) needed to be reduced to include smaller plants in the process. Ultimately, access to results at these smaller plants would serve as a tool to assist in accurately assigning risk.

Some stakeholders emphasized that the plant hazard analysis needs to be pathogen-specific including for emerging pathogens of concern. They gave as an example particular species of *Salmonella* that are frequently linked to food-borne disease outbreaks. It is their perception that the Agency can not/does not consider these species an adulteration, so takes only minimal enforcement actions to prevent them. They request that the Agency take a more assertive position with new

emerging pathogens, like these particular *Salmonella* species, declaring them to be adulterants when identified in meat and poultry products and linked to food-borne illness.

5. Use of Industry Data

Throughout the deliberations, many stakeholders from diverse interest groups suggested using accurate industry data to supplement FSIS data in calculating both establishment risk control and inherent product risk. Stakeholders recognized there are obstacles to obtaining such data and divergent points of view were reflected in suggestions for overcoming such obstacles. For example, some of the industry stakeholders, while supportive of sharing data with FSIS, expressed concern about being penalized for sharing information by receiving more non-compliance reports (NRs), which would ultimately have a chilling effect on sharing data. Other stakeholders expressed concerns that industry might “self-select” which data and how much to share with FSIS, which might not provide an accurate or complete picture when trying to determine risk.

6. Use of Positive Data

While most of the stakeholder discussions were about “negative” data, or data indicating a potential problem (e.g., pathogen testing results, NRs with public health implications, enforcement actions, etc.), some stakeholders suggested FSIS use “positive data”, or data to reflect positive actions or results (e.g., third party audits or PBIS tasks performed successfully), as well when assessing establishments. They suggested that FSIS might find that a given establishment is more accurately categorized by examining positive compliance data associated with that facility, in addition to other information indicative of non-compliance. They also noted that using positive performance factors as a gauge of risk control would reflect on the success of the meat and poultry production process and the level of cooperation between FSIS and industry.

7. Data Infrastructure and Data Integrity

During discussions with stakeholders (certainly by the end of the first day of the Public Workshop), it became apparent to all in attendance that the RBI system being proposed will require significant amounts of data. Some of those data are currently available, some are not. Some are accessible via electronic databases, some are not. Without such data (and a structure for managing it) as well as an understanding of how these data are made available to the public, many stakeholders are concerned that FSIS will create a system that does not accurately reflect the actual risk of food-borne illness to the public.

Given the importance of the data collection/management/analysis system to support a robust RBI program, some stakeholders (again from diverse perspectives) expressed significant concern that such a system and infrastructure do not appear to be in place. Further, since a comprehensive infrastructure system could take a few years to build, it was suggested that implementation of RBI should wait until a comprehensive, verifiable traceability system and a modernized computer infrastructure system is in place, capable of collecting, analyzing, and sharing data throughout FSIS.

Some Stakeholders also indicated concerns about data integrity and reliability and the lack of controls in the current PBIS system. They concluded that FSIS should do a thorough assessment of PBIS before moving forward. One consumer group emphasized the utmost importance of data integrity in any risk-based inspection system. For this stakeholder, the four building blocks of a

robust RBI system are: 1) comprehensive attribution data; 2) measures of the actual prevalence of pathogens in meat and poultry products; 3) enforceable scientific performance standards; and 4) data integrity. Data integrity was particularly emphasized by a stakeholder who said, “Without data integrity, the validity of the system will always be in question.” To ensure data integrity, this stakeholder suggests the following four elements, the answers to which must be addressed affirmatively and verifiably:

- Relevance – Will the data address the question that needs to be answered?
- Accuracy – Are there sound data collection/management practices and appropriate analysis methods?
- Timeliness – Are data shared in a timely manner?
- Credibility – Is there sound interpretation and transparency?

8. Subjective Versus Objective

Throughout the conversation about data, and in particular during discussions about the use of NRs as indicators, stakeholders raised the question of how to integrate subjective versus objective data into final decisions about risk allocation. In particular, stakeholders emphasized that the more objective the data, the more defensible the decisions about allocation of resources, while the more subjective the data, the more controversial the decisions. Stakeholders had different views on: a) whether current data points, such as Food Safety Assessments (FSAs) and NRs or internal industry information are objective or subjective, b) whether they should be included in the algorithm determining risk, and c) whether and how they could be made more viable (e.g., through standardization or audits) as relevant data. Since all stakeholders may not agree on the process for determining risk or the actual categorization of establishments, some stakeholders suggested that it would be important for FSIS to have a well-defined process for conflict resolution.

D. **Perspectives on Stakeholder Input Process**

1. The Process So Far

As mentioned above, many stakeholders stressed the importance of a cooperative and collaborative approach to the development of an RBI system. Some expressed appreciation for FSIS efforts to include stakeholders in the evaluation process for the proposed RBI system. Stakeholders also raised wide-ranging concerns about the public involvement process to date.

A number of stakeholders from all interest groups expressed frustration that they had no sense of the Agency’s big picture vision. These stakeholders indicated that they found it impossible to assess the overall concept, the specific papers, or other presentations on PIR and ERC without a clear picture of the vision and an understanding of the Agency’s willingness and authority to achieve it. Some stated that they found it “demeaning” and “insulting” to be asked to comment on the papers without more details on the concepts, an understanding of the context in which they would be applied, or an explanation of how these ideas will improve public health and food safety.

While some stakeholders – from diverse interests but tending to come more from representatives of industry and academia – lauded FSIS for being as transparent as possible in developing the concepts, most others emphasized the need for more transparency in terms of the Agency’s interests, the scientific process to support its efforts, the various internal working groups, and the experts

involved in evaluating the algorithm, its parameters, and its applicability to the meat and poultry processing industry.

Many stakeholders, particularly consumers, state inspectors, and FSIS employees, expressed their skepticism about the stakeholder input process. Some said it appeared to them that the majority of decisions were made before consulting stakeholders, and they faulted FSIS for not bringing stakeholders into the process sooner. Some suggested the FSIS was just “checking off the box” of stakeholder consultation to “push through meaningless change,” so they can “declare improvement with food safety” for this Administration. Still others asserted that FSIS is simply using the process to look for criteria to amend federal acts so that inspectors will not have to visit plants every day.

One group of stakeholders expressed their displeasure over their perception of a lack of candor in the process. They point to the Agency’s statements and assertions that every processing plant is visited once per shift by an FSIS inspector, and that NRs are written by inspection personnel for every regulatory violation. These stakeholders provided information they believe contradicts each of these assertions and, therefore, they conclude the Agency is not being candid with this or other information.

2. The Process Moving Forward

Although many stakeholders from all interest groups raised strong concerns about the transparency of and access to the process to develop RBI to date, almost all stakeholders were united in their belief in the importance of real dialogue, and see such a dialogue as critical to getting acceptance on (and real engagement in) an FSIS RBI program from the unions, public health groups, consumer organizations, scientists, industry, and other stakeholders. They urge the Agency to provide more opportunities to comment on the various aspects of its RBI program as the Agency continues to design it and moves towards adoption and implementation of this new system.

Stakeholders used several instructive phrases to describe their criteria for a desirable stakeholder input process: “unbiased examination of these issues,” “meaningful debate, with data to back up what is said,” “open dialogue, with opportunities for all stakeholders to speak,” and “equal representation of stakeholders.”

Several stakeholders stressed the importance of ensuring that inspectors are able to provide frank input into the planning, implementing, monitoring, and evaluating the proposed RBI system. One stakeholder requested that comments from inspectors be made available to the public.

Some stakeholders offered specific suggestions for the type of stakeholder input process they would like to see moving forward. Several suggested a process similar to the one FSIS used in developing the Pathogen Reduction/HACCP rule in the 1990s. This 18-month process included seven information briefings; three scientific and technical conferences; a two-day public hearing; six issue-focused public meetings; a Federal-State conference; and a Food Safety Forum chaired by the Secretary of Agriculture. In the view of one stakeholder, the process used for the HACCP was transparent and inclusive, offered multiple opportunities for insights to and dialogue about the propose rule, and encouraged the participation of all interested stakeholders throughout the process.

One industry representative recommended that FSIS create a committee to publicly debate the various components relevant to a RBI system. He suggested that the committee consist of a broad-

based coalition of FSIS personnel, equal representation from large, small, and very small plants, “unbiased” scientists, consumer representatives, microbiologists, and others.

Consumer groups requested FSIS engage in a notice and comment rulemaking process. These stakeholders were concerned about the newspaper article in *Food Chemical News* that indicated FSIS plans to roll out its RBI system sometime during the first quarter of 2007 using an internal directive or notice to inspection personnel, without providing notice in the *Federal Register* and opportunity for public comment.

III. PRODUCT INHERENT RISK (PIR)

A. Comments on Specific Aspects of Product Inherent Risk

After reviewing the paper on *Measuring Product Inherent Risk for Risk-Based Inspection*, stakeholders from diverse perspectives generally agreed with the concept of considering the inherent risk of product produced by establishments when allocating inspection resources. Several stakeholders saw the movement away from the use of a Hazard Coefficient or Hazard Control Coefficient to a consideration of a combination of variables such as species, process, and volume as a step in the right direction in developing establishment risk profiles. Some felt that the new approach could be particularly helpful to smaller plants.

Though stakeholders supported the overall concept of measuring inherent product risk, they all struggled to respond to questions about the paper. As mentioned earlier, stakeholders felt they did not have sufficient information about FSIS’s larger vision for risk-based inspection against which to evaluate either the concepts outlined in the paper or their potential effectiveness in helping to achieve FSIS’s vision. All but one stakeholder group raised concerns about the expert elicitation process, and some were unable or unwilling to discuss the paper without more details on this process. As one stakeholder put it, “We are being asked to judge the process without being able to evaluate the results of the process.”

In these early discussions, stakeholders also expressed the need for more clarity about how inherent risk would be determined and how it would be used in the “real world.” For example, stakeholders wanted a better understanding of how the concepts presented in the inherent risk and risk control papers would be integrated, and how they would impact inspection activities “on the ground.” They asked for more details about the values used in the algorithm, scientific validation for the numbers used in the paper, and the meaning of “measurement of central tendency.” They also requested concrete examples of algorithm values for specific product/process combinations and for various plant sizes. One stakeholder suggested that FSIS run more comparative analyses that would show the challenges in using the algorithm and whether it would work in “real life” or “on the ground.”

The following sections provide a summary of information from the pre-workshop discussions with stakeholders concerning the product inherent risk (PIR) algorithm, volume, and implementation considerations. The section on stakeholder views about the expert elicitation contains information from pre-workshop discussions with stakeholders, the Public Workshop, and electronic input.

1. The Algorithm

In the discussions with stakeholders, some felt the algorithm was “too simplistic” and did not incorporate all the relevant factors, such as historical data, risk assessment data, food attribution data, modeling, published literature and other background information, and post-processing hazard. On the other hand, some stakeholders in the public health sector thought the algorithm was, as they said “...fine as is – not too complex and not too basic...just on the edge of being too cumbersome. If there are too many factors you dilute the value.”

Stakeholders from public health, industry, and academia expressed the view that FSIS should put less emphasis on species and more emphasis on process, since that is where most problems occur. They also noted that with further processing or with ready-to-eat (RTE) products, the effects of species are not that relevant.

One stakeholder thought there was too much emphasis on product, again because it is not so much the finished product as what the product goes through that is important. This stakeholder also thought that risk control is more important than size or the product itself.

Stakeholders called into question several of the statements made in the PIR paper. One academic called “dead wrong” the statement about *Listeria monocytogenes* (*Lm*) on Page 6, line 3: “Thus, species are likely irrelevant to the risk of contamination of processed product exposed to the environment.” He stated that his institution had found that *Lm* grows much better in turkey and chicken than beef or pork, and that there also have been *Lm* outbreaks associated with poultry deli meats.

Two stakeholders took issue with the statement on Page 5, last paragraph, first sentence: “...there is more risk in cooking poultry than in cooking meat, owing to the generally higher incoming load of pathogens on raw poultry.” One from industry called it an overgeneralization, since without current baseline studies, it is not clear that incoming pathogen loads are higher, and cooking processes are designed to take these higher levels into account. The other, an academic, stated that there should not be any difference between poultry and meat - because USDA has set up a process for dealing with problems. In his view, something is wrong with the logic if turkey still ends up being “penalized.”

Some public health experts noted, in regard to the statement on page 4, 1st paragraph, last sentence, regarding “averaging the variables,” that if one of the products is high risk, averaging should not result in diminishing the risk of that product.

2. Volume

In addition to comments on volume received in response to the specific questions posed by FSIS at the Public Workshop (see below), stakeholders made the following comments about plant size categories and data collection.

Some stakeholders representing FSIS employee, industry, academia and public health groups agreed with the need for a volume variable, but thought the three categories of very small, small, and large were too limiting, particularly because of the wide size variation in small and large plants. One suggested breaking both the small and large categories into two, for a total of five categories. Another recommended a volume variable range from .01 to 10.0.

Several stakeholders also emphasized the need to close the data gaps on the quantities of product coming out of establishments. One consumer group noted that the September 2006 OIG report found that the PBIS system does not collect data on production levels or operating schedules, and that this lack of data caused the Agency to exclude establishments from the sampling frame for *Salmonella* pathogen reduction testing. Another suggested that FSIS use the plant profile establishments fill out and ask for an estimate of volume each year.

3. Implementation Considerations

During discussions, stakeholders raised several points about how inherent risk should be taken into consideration when implementing risk-based inspection. One stakeholder stated that the effort should be based largely on a risk assessment that risk/ranks all meat products across all pathogens, similar to what has been started with *Lm*.

FSIS employee and industry representatives pointed out the need for periodically updating the PIR, because of changes in products being manufactured (for example, many companies are making products with anti-microbial properties now) and fluctuations in the relative volume of production. Some also noted that weather is a factor for both poultry and beef, and that incoming pathogen loads on carcasses can change with the seasons.

4. The Expert Elicitation

During our discussions with stakeholders, through comments in the plenary and small group portions of the Public Workshop, and in electronic comments received before and after the Public Workshop, stakeholders raised a wide array of concerns about the expert elicitation process FSIS used to collect data on the relative risks posed to public health by various types of processed meat and poultry products. Some of the requests for information about the elicitation process arising out of early discussions were later addressed by FSIS through information provided on its website and at the Public Workshop. As with several other issues addressed in this report, stakeholders' thinking about the elicitation process evolved as more information was presented. The following paragraphs describe the concerns raised by stakeholders, both before and after the receipt of additional information on the process, as well as stakeholder suggestions for additional expert elicitations.

a. Concerns About Elicitation

Transparency. Most stakeholders first learned that FSIS was using expert elicitation to collect data for use in the product inherent risk (PIR) algorithm when they read the PIR paper in preparation for formal discussions with RESOLVE, or when the paper appeared on the FSIS web site. As a result, almost every stakeholder group raised concerns about what they saw (and for some, continue to see) as the lack of transparency about: who was involved; who chose them; what information and assumptions they were given; what questions they raised; how and by whom the questions were addressed; and whether the experts agreed with the process categories. One industry group made the point that: "Meaningful incorporation of input from industry and all other stakeholders into the FSIS RBI system will result in a more cooperative and collaborative approach to meat and poultry inspection." They emphasized that the Agency "must address the lack of transparency to date in improving the volume variable and defining the impact of interventions."

Relying on experts instead of data. Several stakeholders, particularly academics, consumer groups, and state inspectors, expressed the concern that FSIS is putting too much reliance on the opinions of a group of experts about how to define and assign risk, particularly when there is not adequate data to establish risk. In their view, although the parameters the experts come up with may be logical, there are no data to prove that they are the right parameters - no data to say what they picked translates into an overall impact on public health. One expressed distain for a process that assigns risk by, “gathering opinions, averaging them, and using them as basis for doing risk assessment.” Another thought FSIS would have difficulty defending such a system – set up with no data - if a company ever sued for being ranked higher risk and therefore needing more inspection.

Some stakeholders expressed the view that the experts should have worked with the best available public health data, including product attribution data, instead of operating from their own experiences. They asked if the science used was correct, and suggested that the results of the elicitation be crosschecked with data in the public domain.

The experts. One of the biggest concerns raised by almost every stakeholder was the composition of the expert panel. Some of these stakeholders pointed out that, of the 23 experts, four were tied to major food companies, and eight were from land grant universities with ties to the industry. One noted that the two public health experts were employees of other U.S. government agencies.

Assumptions. Stakeholders raised several concerns with the assumptions expert were asked to make in scoring the products according to relative risk of illness, per serving, the product category posed. Most particularly, as is discussed in greater detail in the next section, several stakeholders were concerned about the requirement that the panelists assume that the consumers eating these products were healthy adults. From the perspective of these stakeholders, women, children, the elderly, and the immune-compromised are at highest risk of food-borne illness, and the risk to these consumers should have been taken into account.

One stakeholder felt there was a built in assumption that the consuming public is largely uninformed regarding basic hygiene and food preparation knowledge, and that this could result in over penalizing companies.

Another stakeholder also questioned the appropriateness of instructions to discount products prepared at the retail or institutional level and to assume the incoming source material comes from a firm with “average or typical food safety controls.”

Scope. Several stakeholders raised questions related to the lack of an upper boundary for the experts’ scoring. They expressed the view that the parameters given to the experts were vague, as borne out by the extreme range of the scores rated by the experts, making any comparison between experts virtually impossible. Some felt the discrepancies in scoring showed either a lack of agreement or a lack of understanding of the product ranking process the panel was charged with completing.

Some stakeholders expressed concern about the lack of clarity as to whether the experts were concerned with controllable or uncontrollable risks in their determinations and whether this could skew their perspective and affect Agency decisions.

b. Suggestions for Additional Expert Elicitations

Most stakeholders felt strongly that the expert elicitation should be redone, with a broader group of experts, clear scoring boundaries, and a different set of instructions. The following are some of the specific suggestions put forth by stakeholders.

Redo the elicitation. While some stakeholders thought the first expert elicitation was a good start, most agreed that the rankings needed to be reexamined by another group of experts. Some saw a new elicitation as an opportunity to gather additional input from industry, public health officials, and knowledgeable academic experts in food safety to further define PIR. One stakeholder thought that the risk-ranking should be reviewed on an annual basis to reflect new and emerging food products.

To build transparency and trust in the process, some stakeholders asked that FSIS provide an explanation for disagreement among the experts or background material on their conclusions. Others emphasized the need for an independent (i.e., not within USDA) peer review of the elicitation results before they are made public.

Since the data from the panel of experts is extrapolated to define risk categories of a broad populace, one stakeholder suggested it would be valuable to convene several such panels, possibly focusing on particular foods, in order to arrive at a more realistic and scientifically defensible consensus.

Industry groups suggested a new expert elicitation be conducted face-to-face rather than by correspondence in order to facilitate the full exchange of ideas needed to develop a consensus on and a rational basis for the risk rankings.

Involve additional experts. Stakeholders, particularly those representing consumer groups, suggested that a new panel include food-based experts from industry; experts from consumer foods groups; an epidemiologist; independent public health experts; academics with medical expertise; and medical doctors. One group stressed that the panelists should not have a financial stake in the outcome of the risk ranking process, so they could provide a more public-oriented perspective.

Incorporate data in the public domain. Several stakeholders, including industry and consumer groups, suggested that attribution data and the Centers for Disease Control and Prevention (CDC) results be included in a new elicitation.

Set clear boundaries for scoring. To help normalize the data and reduce the number of outliers whose concerns may otherwise be lost, stakeholders suggested that the experts be asked to re-rank the food safety risks of products using a common scale predetermined by the agency. Some suggested ranking on the basis of inherent risk rather than on relative risk of illness, with someone other than the experts setting the weighting to be used. This approach would eliminate the need to justify a median.

Stakeholders also suggested that experts be asked for their input on whether the initial list of product types is complete, and whether or not to use the median of the scores.

Include a new set of instructions. Stakeholders suggested that FSIS provide clear and unambiguous directions on how to score the relative risk of various products, including the following:

- Instruct the expert panel to consider severity, particularly as it relates to vulnerable populations, when ranking the inherent risk of products.
- Direct the experts to provide a rationale for their rankings, including a scientific justification for their reasoning.

B. Comments in Response to Specific Questions Posed at the Public Workshop

In small group discussions at the Public Workshop and in comments submitted electronically after the workshop, stakeholders responded to a series of specific questions related to PIR. In the summary below, it is important to note that most of the comments came from small group reports, with mixed groups of stakeholders. As such, it is not possible to differentiate which stakeholder group offered which comment. Any differentiation noted is a result of electronic comments on the questions from specific stakeholders. Since not every stakeholder group commented electronically on every question, the summary that follows is not a comprehensive comparison of views.

1. FSIS has tentatively decided to use the median of the expert score in the Inherent Risk algorithm. Is there an alternative they should consider?

Stakeholders had different views about using the median of the expert score. Many agreed that the median was the best score, particularly if the elicitation is refined to use definite parameters in the scoring (e.g., high=100, low=1) and all assumptions provided to the experts are valid. An industry group suggested normalizing individual data sets for each expert on a scale of 1 to 100 before using the median score in order to take into consideration the scores of all experts for all products.

Some stakeholders, including a consumer group, disagreed, particularly if there are no boundaries set for the scoring. A suggestion was made to use a formula more like that for HACCP, i.e., likelihood of hazard X severity of occurrence X likelihood of mishandling.

Other stakeholders focused instead on the need to validate the model and results and to put mechanisms in place to get attribution data. Some felt they could not answer the question without more information about the context in which experts came up with their rankings; what FSIS has done to validate the median; or what FSIS intends to do with the number.

2. Thermally-processed, commercially sterile products (e.g. canned products) were not included in the elicitation for scoring by the experts. How exactly should they be fit into the range of Species/Process values now?

Some of the stakeholders expressed the view that, since thermally-processed, commercially sterile products are inspected products, they should be an included category. In fact, in one of the onsite small groups at the Public Workshop, all the participants agreed on this point. However, many other stakeholders disagreed, stating that these products should have their own standard, and that others should not be measured by that standard.

There was almost universal agreement that thermally-processed, commercially sterile products should be considered in the lowest risk category given past meat and poultry inspection regulation, the number of food safety barriers/hurdles built into the process, almost-non-existent food-borne

illness rate. However, some stakeholders thought these products should be considered high risk given the serious consequences if the process breaks down. These stakeholders also expressed a concern that without a high ranking, little inspection would take place.

One Public Workshop small group asked how low water activity shelf stable products would fit into this range of species/ process.

3. If a processed product is to receive further processing at another establishment, how should we account for its inherent risk? If further processed at retail?

Another Establishment. Stakeholders held a wide range of views about how to account for further processing at another establishment. Many stakeholders expressed the view that each plant should stand on its own and that assumptions of relative risk should be based on each plant exercising due diligence in their HACCP and SSOP systems design and implementation. (For example, a plant whose end product is raw ground beef contaminated with *E. coli* O157:H7 would be accountable for high inherent risk, while the cooking plant that receives that contaminated ground beef, would have a lower inherent risk factor because their finished end product is free of that pathogen.)

Many other stakeholders, including industry groups, hold the view that if a product is further processed at another FSIS/State Inspected facility, it should have reduced risk - the same inherent risk as that of finished product. The rationale these stakeholders present is that the product is going into another HACCP program and can be further evaluated for risk at that establishment. Some of these stakeholders believe that when establishments are able to demonstrate that a product is produced solely for the purpose of further processing, and has records to show that the product reached the intended destination, the Agency should consider that information when determining PIR.

Some stakeholders believe the calculated risk should be higher if a product is further processed at another establishment because of “worst case” issues that could develop in transit. Still others think decisions should be made on a case-by-case basis due to a number of factors, including: intended use; likelihood of mishandling; whether or not there is a lethality step at the second establishment; and whether or not the product is post-lethality exposed.

Retail. Stakeholders also disagreed about how to account for further processing at retail. Many expressed the view that once the product leaves the federal inspection system, risk should remain the same whether it is going to foodservice, retail, or consumer. Other stakeholders thought the risk should be higher because the further from the producer, the higher the possible risk.

4. How do we translate volume data collected for each type of processed product produced at each establishment into an exposure variable for that establishment?

Stakeholders approached this question in a variety of ways. Some saw volume as a factor in determining PIR and answered the question accordingly. Others thought it more appropriate to include volume as a component of ERC. Still others thought volume should be considered independently of either PIR or ERC.

Volume as Part of PIR. Stakeholders who consider volume to be a component of PIR, varied in their suggestions for how to factor in volume – on its own, or in combination with one or more other variables (process, product, species).

Some stakeholders expressed the view that risk should be weighted against the volume of product processed. For these stakeholders, a small volume establishment would pose a lesser risk than a larger establishment simply because of the volume produced. Some in this group noted that “batch” volumes may have different inherent risks from continuous line volumes and that the length of time it takes to produce a total volume may impact on the inherent risk of that production system.

Other stakeholders believe volume plus process should determine risk. Some of these stakeholders suggested that volumes be broken down further into each individual process (i.e. individual HACCP categories), and that steps in the process, multiplied by the volume, be considered. In this instance, certain processes that inhibit risk (ex. CVP packaging) would be negatively weighted.

Others would factor in the risk of product in making a determination of exposure. In this case, a large amount of high-risk product shipped, as opposed to a small amount of low risk product, would be an important consideration.

Still others suggested weighing factors based on species and product type. Finally, some stakeholders would consider volume based on process and product group.

Volume as Part of ERC. For several stakeholders, more volume does not necessarily mean more risk. These stakeholders believe volume should be evaluated as a component of the establishment risk control measure. As some who hold this opinion described their view, if all things are equal in plants (based on system design, system implementation, pathogen control, plant history, number of food safety related NRs, and the number and outcome of FSAs), volume would probably not be an issue. On the other hand, if all things are not equal (i.e., one plant has a better system design than another), then volume could be of greater concern.

One stakeholder suggested that FSIS do additional analysis on how to integrate volume data as an establishment attribute or on its own.

Volume Independent of ERC or PIR. Many stakeholders, including consumer and industry groups, suggested that volume be considered independently of both inherent product risk and establishment risk control, so that the two-dimensional model proposed by FSIS would be transformed into a three-dimensional model with X, Y, Z axes. As one set of stakeholders explained it, volume is less significant for lower risk products from plants with better ERC than for higher risk product from plants with poorer ERC and should be variably weighted to reflect this fact.

Defining Exposure. Among the comments from stakeholders were suggestions to FSIS for how to define exposure as well as a series of questions about volume and exposure. One industry group suggested that exposure be expressed as the number of servings per person per year, the number of servings per 100,000 people, the number of servings produced, or some similar metric. In doing so, they believe that, unless the products are going directly to consumers in retail-ready packages, the conversion of volume to exposure is not direct and further processing into other lower risk products at federally-inspected establishments steps must be considered.

Another industry representative suggested that the size of customer base is also important in determining exposure. As this stakeholder explained, a large plant might ship product into many states but have a small customer base of large-scale customers. On the other hand, a medium-sized facility might ship products into fewer states, but have customers of all sizes. In the latter example, in spite of lower production volumes, the customer base can be much greater than a plant with higher production.

Some stakeholders asked if FSIS is defining volume as a single portion size for a consumer or as gross production volume for each plant. These stakeholders also asked if by the term “exposure variable” FSIS means that each product has a portion size/consumer unit/volume and that relates to that product’s inherent risk; or if FSIS is referring to risk definitions of exposure potential.

5. Given that most establishments produce more than one type of product, how should inherent risk data for each establishment be presented?

Some industry groups thought that there should be no automatic answer to this question, because there are a variety of factors to consider, including the nature of the different products, how often they are produced, and the volume percentage of each product. Similarly, some suggested that mapping out where all of an establishment’s products fall on a two or three-dimensional grid would assist in determining risk and also help inspection and establishment staff visualize the risk array for the entire profile of products.

Several stakeholders believed that if an establishment handles or performs multiple species or processes, then that establishment should be assigned the risk level of the highest-risk species or process. Some in this group also felt that processes with more steps and more high-risk steps should be weighted more heavily. Some felt that using the riskiest product to determine inherent risk should be balanced against volume.

Some stakeholders would base inherent risk on types and subtypes of products. Some would base it on process categories. Others would calculate it per product per process per establishment.

One industry group suggested taking the median or mean of all products’ inherent product risk, weighted by production (greater weight given to higher risk rankings), to determine the ultimate product risk measure for the establishment.

Several stakeholders noted that the frequency with which a high-risk product is produced, whether as a result of customer orders or the season of the year, must be considered. Some suggested that ultimately, inherent risk should be based on the percentage of total production or on annual production by product type.

Some stakeholders noted that the inherent risk data would need to be updated when new products are added or removed.

6. To better ensure comparable expert data, we did not ask experts to consider severity of illness that can result from the consumption of contaminated meat and poultry. How should we account for severity of possible illness when calculating the risk inherent to each type of meat or poultry product?

Some stakeholders made the point that, given the high numbers in the rankings for raw products, it appears that some of the experts did take severity of illness into consideration.

Many stakeholders, including industry representatives, expressed the view that severity of illness should be factored in when calculating inherent risk, particularly if a specific product is targeted for consumption by a more-vulnerable segment of consumers (*e.g.*, children or the elderly). Some thought it might be necessary to do the ranking first and then adjust it based on severity. One stakeholder recommended that FSIS take advantage of the experience of risk assessment experts who have done this type of ranking before.

Some of the stakeholders who advocated factoring in severity noted that severity of illness can be affected by several factors, including volume, the type and infective dose of pathogen and, the susceptibility of the consuming public. They spoke of the importance of historical illness data and available food attribution data in determining the severity of any illness, and the need for FSIS, FDA, and CDC to continue to work cooperatively to improve the acquisition and use of food attribution data.

Several other stakeholders hold the view that it is not appropriate to consider severity of illness when calculating the risk inherent to each type of meat and poultry product. Some of these stakeholders stated that it is not possible to predict the severity of illness. Others noted that from a consumer's standpoint, getting sick or dying are both seen as a failure of the food safety system.

Finally, some stakeholders thought severity of illness should be paired with the exposure proxy in some way.

IV. ESTABLISHMENT RISK CONTROL (ERC)

A. General Comments

Stakeholders from diverse groups generally agreed with the concept of considering how best to allocate Agency resources partially based on the effectiveness of establishment risk control efforts. The concepts and aspects of ERC proposed by FSIS that received significant interest and attention include: the potential and process for incorporating additional sources of data, such as industry-generated data, attribution data, severity of potential illness, volume of product handled and processed at establishments, and consumer complaint data not gathered by FSIS; and whether and how to quantify and use different data and information, such as NRs, FSAs, and other enforcement actions as indicators of risk control.

Stakeholders voiced greater frustration with the lack of details about ERC in the formal discussions prior to the Public Workshop, but desire for greater information continued to be expressed in electronic communications following the Workshop. Ideas for different categories for ERC and the

overall algorithm also were submitted in electronic communications. All stakeholders want additional information as to how these variables may be determined, how they will be used in the overall algorithm to develop establishment risk profiles and relative risk rankings, and their collective, ultimate impact in determining inspection effort. The majority of stakeholders wants more information on and details about: a) FSIS's larger vision for risk-based inspection; b) each component within establishment risk control; c) how measures for ERC will be integrated with PIR in an overall calculation of risk; and d) how this combined calculation will be deployed "on the ground."

B. Comments Received in Early Stakeholder Discussions

1. General Comments on ERC

Stakeholders provided a range of comments about the paper developed by FSIS and distributed during the summer of 2006 entitled *Measuring Establishment Risk Control for Risk-Based Inspection*. Because this paper was distributed along with another paper, *Measuring Product Inherent Risk for Risk-Based Inspection*, and stakeholders were asked about both papers as well as their general thoughts on modifying meat and poultry inspection based on risk, comments touched on all of these aspects. Even those comments specific to the basic design of establishment risk control often were couched in thoughts about how this piece fit with product inherent risk and a comprehensive view of what the RBI Initiative is and could be. Therefore, comments in this section overlap with those presented in the previous section on PIR.

Although stakeholders often commented that the paper on ERC was easier to understand than the paper on product inherent risk, they still struggled to comment without more specific details on the components of ERC and a better understanding of the overall goals for RBI against which to measure these components. For example, one group of stakeholders from industry stated that, "It is not at all clear how the Agency's independent determinations about inherent risks and about establishment risk control measures will ultimately be melded together to form a basis for making inspection resource allocation decisions. A numerical score based on the algorithm is the ranking methodology for the inherent risk, but there is no suggestion as to how establishment risk controls will be scored, or whether they should be scored, as a measure of risk. Further clarification should be provided on this point sooner, rather than later." Stakeholders also sought additional information on the Agency's thinking about the use of NRs most relevant to food safety and about how the concepts "will be applied and work in the real world."

Some stakeholders, from all sectors, expressed myriad concerns regarding data. Many stakeholders extensively discussed particular categories of data they thought critical to assessing and managing risk at establishments, including comprehensive attribution data and microbiological baseline data. Some stakeholders voiced concerns that the microbiological baseline data developed from HACCP are woefully inadequate, and cited reports that have made similar assertions (OIG report Nov 2004). Stakeholders stated that attribution data is not being adequately tapped, nor are those sources that do collect attribution data, including the CDC and some of the state agencies.

For some stakeholders, concerns about data were magnified by what they see as the building of a new system for inspection based on an already flawed database. While the concept of determining risk posed by different meat and poultry establishments can be a good step towards highlighting risks in the food production system, they argued that using the current data collected by FSIS,

renders this approach ineffective. Expressions such as “Building a system on a house of cards,” and “Garbage in equals garbage out,” were used in emphasizing these points. Other stakeholders believe that, even if some measure of relative risk could be determined among different establishments using current data, FSIS may not be able to demonstrate improved public health results if it manages risk based on this calculation. Their skepticism was attributed partly to lack of detail in the proposed approach for measuring ERC and implementation of RBI, and the related inability to evaluate specific aspects of the proposed approach, such as how the algorithm accounts for variability of production within and between establishments.

Some stakeholders, particularly from industry, believe the approach to measuring ERC is fundamentally flawed because of the subjective nature of many of the factors. Stakeholders voicing this concern cited NRs and FSAs as “having been and continue to be subject to inconsistent application and interpretation of existing regulatory requirements and are very susceptible to the influence of inconsistencies among inspection program personnel.” Some advocated for a “correction factor” to address this potential problem and ensure proper allocation of inspection resources. Some stakeholders argued that the algorithm must exclude any subjective information/data in order for it to have “scientific integrity.”

2. Comments About the ERC Paper

While many stakeholders concentrated their comments on risk-based inspection broadly and the Agency’s approach to moving toward a more risk-based inspection system, some did provide thoughts on the ideas outlined in the paper.

The paper, *Establishment Risk Control for Risk-Based Inspection*, proposed five categories of components:

- System Design
- System Implementation
- Pathogen Control
- In-Commerce
- Other Performance Indicators

Some stakeholders approved of the five different categories and thought the paper and ideas were, “well put together.” One person stated that FSIS, “Is really trying to understand what is going on at the establishment.” Another stated, “This paper is on target,” and liked the five measurement objectives. Other stakeholders commented, “The five risk control realms identified by the Agency have merit and mirror those put forth by the RBI Coalition.” Others commented on the importance of weighting different factors, suggesting some were more important than others, are more quantifiable, or are more readily attainable.

A few stakeholders commented that the break down of the objectives for each component was helpful and the basic logic for the structure and inclusion of each of the different components received support. Specific elements of design were applauded, such as: the inclusion of food safety systems design and implementation; a new approach to NRs, including the effort to determine and focus on those that have food safety significance; and the general multi-dimensional considerations in measuring ERC, which for many stakeholders reflects the complexity of assessing what is happening at an establishment and associated efforts to control risks affecting food safety. Again,

there were many comments of concern with some of the details of how the various components are being calculated or factored into an algorithm for determining risk.

A few stakeholders, especially from industry, were most positive about the first two components, food safety system design and food safety system implementation. Many support the concept of breaking these components out separately, concurring that well-designed systems implemented poorly or poorly designed systems implemented vigorously will fall short of improving food safety.

Specific aspects of different components, in particular, NRs and FSAs, were discussed at length by some stakeholders. Stakeholders also made suggestions for additional categories of information, as well as sources of information to include in determining ERC. They also recommended extensive training of personnel and greater communication between industry and Agency staff as critical to a successful RBI system.

3. Specific Comments on Components of ERC

Stakeholders offered a variety of comments regarding these categories. Some comments were specific to the components, others included suggestions for other information to be considered.

a. System Design

The proposed intent of this component is to, “Assess the intrinsic ability of an establishment’s food safety system to control risks.”

Stakeholders had a variety of comments on system design. One consumer group stakeholder noted that they were glad to see that FSIS is doing more thorough review of establishments’ hazard analysis in scrutinizing food safety system design. Others wanted to see more specific hazards tackled, such as commodity-specific targeting in HACCP plans for particular pathogens. Examples given included *Salmonella* resistant to chloranfenicol in ground beef HACCP plans, and for raw poultry, *campylobacter* and *Salmonella*. It was suggested that as additional pathogens are identified as causing human illness, they should be added as well.

One stakeholder suggested that food safety system design needs to include an analysis of inputs and the potential level of contamination, as determined by the nature and source of materials received and the likelihood they are contaminated when received. All inputs need to be reviewed, not just “end-of-the-pipe” product. This stakeholder suggested that, “If FSIS only looks at carcass at the end of the line, industry will focus on ensuring the carcass is clean at that point but won’t pay attention to scraps that go for ground beef.”

Food Safety Assessments (FSAs). Many stakeholders commented on FSAs, and these comments were very diverse in terms of detail and enthusiasm for FSAs’ role in evaluating the effectiveness of establishments to control risk. Several comments were in direct conflict. For example, while some stakeholders believed that the flexibility built into these assessments are a positive means for FSIS to work with and provide incentives to establishments to improve their efforts to control food safety risk, others view this flexibility as too subjective and, therefore inherently problematic.

Some stakeholders, especially FSIS employees, believe FSAs have improved substantially over the last several years and are very effective tools for determining an establishment’s efforts to control

risk. These stakeholders supported the use of FSAs, in combination with appropriate incentives and enforcement actions, to accomplish enhanced food safety practices.

One industry stakeholder commented that: FSAs waste a tremendous amount of industry time on non-food safety problems; results one day contradict results from the day before; and FSAs can take ten days, whereas industry audits can be done in two days. From this stakeholder's perspective, FSAs are auditing regulations, not food safety.

Other stakeholders expressed concern with FSAs, citing a variety of factors they view as flaws in the system that render FSAs ineffective as a major component for evaluating an establishment's ability to control risk. These factors include perceived subjectivity; a lack of consistency due to inadequately qualified and trained personnel; the infrequency of FSAs; and the fact that, when challenged, FSAs often are changed.

Consistency. Some stakeholders while agreeing that FSAs have value as an audit of a food safety system, noted that the Agency, "Should be aware that there has on occasion been a great deal of variation in the quality and applicability of conclusions drawn on the basis of FSA findings." They further commented that the lack of consistency in the audit process and in the conclusions drawn from FSAs will, "compromise the value of this tool when applied across numerous establishments that will ultimately be compared for purposes of inspection resource allocation." These stakeholders highlighted their concern with the example of an establishment that received a Notice of Investigation and Enforcement (NOIE), because of clerical paperwork errors having no bearing on the efficacy of their process, following an FSA that documented an effective validated and verified food safety system. This establishment had experienced no recalls, no enforcement actions, and exceptionally few NRs.

As one stakeholder who sees the value in using FSAs to help determine risk put it, "Everyone has to call things the same way." Right now, this stakeholder explained, some areas of the country have higher numbers, but that does not necessarily mean there is greater non-compliance. These higher numbers could be the result of a variety of factors, and not necessarily relevant indicators of greater food safety concern. Another stakeholder stated that FSAs should not be used, because the lack of uniformity could result in good plants being given a higher level of inspection and bad plants could receive too little.

Other stakeholders cited Agency guidance as the cause for the inconsistency in the implementation of FSAs. They stated that, "FSIS directions and emphasis for Enforcement, Investigation, and Analysis Officers (EIAOs) can change on a monthly basis, making it impossible to compare FSAs from even six months ago to FSAs today." They further suggested that, "There has been a 180° turn in the last six months regarding how to conduct FSAs. It's not the food science that changes, it's the political science."

Training. Stakeholders, particularly from industry, suggested that current inspection personnel are not adequately qualified or trained to conduct key components (such as FSAs) being considered to assess establishment risk control. They note that validation and verification of establishment food safety systems should be performed by properly trained program personnel who are properly managed on a constant basis to ensure effectiveness and compliance. While EIAOs have special training to do FSAs, other inspection personnel do not. If FSAs become a more significant component, then training will have to bring more personnel up to speed with qualifications to do

this work. One stakeholder asserted that many inspectors are not qualified to evaluate food safety systems due to minimal training in food safety and systems analysis. Another suggested that veterinarians on staff take more of a role in conducting FSAs as they have basic qualifications and skills that, coupled with training, could do this work.

Implementation. Stakeholders also raised questions and concerns about FSAs with regard to the implementation of RBI. For example, some stakeholders posed the following questions: 1) Can FSIS utilize FSAs that have already been performed in making decisions about resource allocation, or do new and current FSAs have to be conducted? 2) Since the Agency lacks the resources to perform new FSAs in all establishments in the near future, how will the absence of a current FSA impact the allocation of resources for individual establishments? 3) Will FSAs be based on something developed jointly by the establishment and the Agency?

Another stakeholder mentioned concern that the data available to make this concept work is not strong enough or defensible.

b. System Implementation

The proposed intent of this component is to, “Assess how well and how consistently establishments implement their food safety system.”

A couple of stakeholders thought this component was well described and, as mentioned above, were enthusiastic that Food Safety System Implementation is being seen as a separate but equal measure with Food Safety System Design. As a group of industry stakeholders stated, “We agree with the Agency determination that a good food safety system that is poorly executed is not robust, nor is a poorly designed system that is properly executed.”

The vast majority of comments were directed toward NRs. While some stakeholders would rather that NRs not be considered at all, believing that these records and data from them are too subjective, others believe NRs can represent a relevant point of information in determining an establishment’s ability to control and/or address risk. Many stakeholders supported the Agency’s effort to evaluate NRs to determine which ones are truly pertinent to predicting food safety outcome. Some who hold this view still have concerns with how NRs are being viewed and think FSIS needs to do more work to narrow down which NRs are relevant to food safety.

Some stakeholders raised questions about FSIS’s additional efforts to delineate NRs, including: 1) What is the Agency looking for? 2) What are the standards? 3) What questions are they asking? and 4) Who are they consulting with? One stakeholder suggested that because NRs are legal documents, meant to hold up in court, they do not highlight food safety issues effectively.

In addition to discussing the variability of NRs in terms of their relevance to food safety, stakeholders also commented on variability in terms of quality and quantity. Some suggested that good inspectors may write many NRs, but quantity may not mean that a plant has chronic food safety issues. In fact, these stakeholders stated that, “Some of the best plants get the most NRs.” Stakeholders suggested a variety of reasons inspectors sometimes write many NRs. In addition to multiple NRs indicating unsafe processing activity, they can also be attributed to other issues. Some stakeholders point out that in some instances higher NR activity occurs when inspectors know there is going to be an FSA conducted or that their supervisor is coming to an establishment. One

stakeholder said, “You can actually see the bumps in NRs over the months.”

Alternatively, some stakeholders noted that low numbers of NRs might have a variety of explanations. For example, a stakeholder explained that some inspectors have an aversion to writing NRs because they are not confident in their writing skills and do not want others to see and critique their NRs once they have been entered into the computer. Instead of writing NRs, these inspectors talk about problems in weekly meetings with plant managers. In this instance, as these stakeholders point out, the lack of documentation does not equal excellent food safety practices at establishments.

Stakeholders offered several suggestions (in addition to the FSIS data analyses mentioned in the paper) for next steps, including: reclassifying and clarifying the impact of those NRs that are not associated with food safety (in other words, test the impact of focusing on subsets of NRs with other categories first, before deploying an approach that assumes focusing on food safety relevant NRs will do what is intended); review of the process for a new classification system and its implementation by all stakeholders; and periodic review and training of the work force writing the NRs to minimize variability. Other stakeholders suggested going to the work force for their input on re-classifying NRs to help identify which ones are most relevant to food safety.

Stakeholders also discussed: 1) the necessity of linking NRs to FSAs; 2) making NRs a small part of the equation (i.e., weighting it minimally); and 3) explicitly defining how non-compliance has food safety risk.

Finally, several stakeholders expressed interest in additional information and involvement in the efforts to re-classify NRs and determine how they will be factored into measuring establishment risk control. Associated comments included, “We encourage the Agency to involve all stakeholders in the NR data analysis process,” and, “The FSIS effort to identify the types of NRs that are more predictive of adverse outcomes should be the subject of public discussion in an open process.”

c. Pathogen Control

The proposed intent of this component is to, “Assess how well establishments control microbiological hazards.”

Many stakeholders expressed interest in pathogen control. Some stakeholders believe that this component is the most important because it is an objective measure of success or failure of controlling food safety risks, and it can be directly relevant to food safety. Other stakeholders expressed concern that there was too much emphasis on pathogen control, suggesting that, “Absence of evidence is not evidence of absence,” and proposing, instead, a greater emphasis on process control.

Several stakeholders raised concerns about whether this approach - the overall algorithm - will adequately conduct, analyze, and based on the analyses, manage risk. For these stakeholders, the effective use of pathogen control requires outcome measures; and for a public health benefit to be realized and documented, outcome measures must be evaluated against standards. They further commented on the challenge the Agency faces in establishing standards given current statutory authority and the outcome of the Supreme Beef case. In their view, without standards, pathogen testing and control is less potent as a tool for controlling risk and demonstrating overall

improvement in food safety.

Some stakeholders had very specific comments concerning *E. coli* testing. One stakeholder commented that generic *E. coli* testing is not relevant to food safety because, “It is not a good scientific test, plant folk do not know how to do it right, and they do not know how to interpret the results.” Another stakeholder stated that if the testing is generic and does not indicate which kind of *E. coli* is found or where it is found, it is irrelevant. Only if the testing is specific to *E. coli* O157:H7, or any other *E. coli* that is known to cause food-borne illness, and specific to the finished product, it is not relevant. Another stakeholder with a similar view stated that plants may receive raw meat for further processing (from plants that have letters on file saying they have interventions in place), and if testing finds *E. coli* O157:H7, it doesn’t necessarily mean it is that processing plant (as opposed to the plant from which the raw meat was received) that has risk control problems.

Other stakeholders commented that the Agency should take into consideration testing conducted by companies because, “FSIS could never do enough testing on its own to ensure safety.” Further, “They have to demonstrate that product coming off the line meets microbiological standards. This should be done every day and should be part of the materials inspectors check every day. This should be separate from, not part of, compliance.”

d. In-Commerce

The proposed intent of this component is to, “Assess how well establishments prevent shipping contaminated, adulterated or hazardous products.”

Many stakeholders commented on this component and, in particular, on the consumer complaints and the Consumer Complaint Monitoring System (CCMS). Some stakeholders from all sectors were very much in favor of this information being included; several wanted to see this part of the algorithm bolstered by additional information that currently is not available to the Agency, such as complaints that go directly to companies and attribution data or “traceback” information. Others commented on and were supportive of the paper’s reference to verification of consumer complaints, stating that these steps are necessary to ensure complaints are valid and have public health significance. Many stakeholders were very interested in information about the specifics of how the Agency will determine which consumer complaints have food safety significance, including greater detail on the scientific basis on which the information will be reviewed and assessed. It was suggested that, “Public review and vetting of the findings with respect to consumer complaints is necessary.”

One stakeholder commented that the paper is inaccurate in describing USDA’s use of the CCMS. He stated “USDA does not get involved with consumer complaints unless they make their way to the Agency, and not all consumer complaints are in the database. There are plenty of complaints from small towns that never make it in to the database.”

Some comments touched on other in-commerce information. A stakeholder who is an FSIS employee stated that, “We don’t have enough people in the field to look at transportation and shipping problems.” Another stakeholder discussed the need for more monitoring and regulation of the trucking industry, including temperature control and other factors important to food safety.

e. Other Performance Indicators

The proposed intent of this component is to, “Assess other indicators of how well establishments control food safety risks.”

Many stakeholders agreed that other performance indicators should be considered in measuring establishment risk control. Some commented on the specific factors listed in the paper, particularly with reference to *E. coli* tracking (System Tracking *E. coli* 0157:H7 Results - STEPS) and Enforcement Actions, while others listed additional factors they thought should be included.

Stakeholders discussed the importance of *E. coli* monitoring. Some strongly advocated that FSIS establish the capability to trace back *E. coli* to the sources of the problem. One wanted to know in very specific terms what methodology the Agency intends to use (as stated in the paper) to “take a closer look” at STEPS information, stating that, “FSIS has to have a bottom line for measuring risk control that indicates which establishments pass and fail.”

With regard to enforcement actions, one stakeholder stated that, “The paper fails to state that inadequately designed food safety systems are currently a basis for Agency enforcement action to withhold the mark of inspection or to suspend inspection altogether.”

Several people proposed comprehensive lists of other performance indicators that should be included in measuring establishment risk control. One stakeholder suggested ERC include volume, consumer consumption data, food safety design, and implementation, validation, past history (compliance results), FSIS sampling, and consumer complaints. Another stakeholder offered several other factors in addition to those listed in the paper, including bringing illness data into the analysis, compliance with performance standards, and sanitation and environmental testing. This stakeholder also suggested that the Agency consider how to use the USDA mark as an incentive for the industry to do more food safety, and that it review how different establishments define product “lots.”

4. Other Factors

Other factors not listed in this particular paper and discussed frequently by stakeholders included volume, severity of illness posed by different pathogens, and interventions. Some suggested that FSIS consider the longevity and degree of training of establishments’ work force. They stated that, if establishments make efforts to educate and train their workers to properly perform their tasks, this should be taken into account in any measure of establishment risk control; and low turnover of staff could be an additional sub-category.

Volume. As was discussed in Section III in the summary of answers to Question 4, many stakeholders advocated for consideration of volume of product handled by an establishment. Some discussed volume of output and others emphasized volume in the context of the number of consumers potentially affected. Many examples were given to illustrate suggestions or perspectives. Several stakeholders made the point that those establishments that produce high volumes of product have the potential for affecting many more consumers. For example, a plant that produces twelve to fifteen million entrees per week has the potential for a food safety impact on 250 million people.

Some people used examples to illustrate different considerations and challenges in determining which establishments pose greater food safety risks. One stakeholder noted, “A plant with five cooked meat lines has the potential to be far more risky than one with one cooked line.” And, “A very small plant that runs one to two days per week, but produces everything imaginable, cooked

and uncooked is far more risky than larger plants with one product.” He also cited the example of a small plant that produces 100% of one large retail company’s Cornish hens and the associated significant potential impact should a food safety hazard occur.

Many stakeholders discussed volume in the context of the other paper addressing product inherent risk, and stressed the importance of integrating the two concepts together. Comments on volume and severity of illness often linked establishment risk control and product inherent risk together. One stakeholder commented that establishment risk control (with certain products) should be given much more importance, because, “that is where FSIS has more control anyway.”

Interventions. Many stakeholders discussed interventions, and comments ranged from enthusiasm to skepticism to ambivalence for consideration of interventions in the algorithm to determine establishment risk control.

Some stakeholders suggested that if a plant can produce a product, using interventions, that tests free of pathogens, verified by microbiological data, then this information is a good way to differentiate between different establishments when considering how best to allocate resources. One stakeholder suggested that the *Listeria monocytogenes* Risk Assessment illustrated that the intervention strategies have the highest impact on reducing risk and, therefore should be taken into consideration in determining an establishments efforts to control risk.

Some stakeholders were ambivalent about factoring in the use of interventions as a consideration in determining establishment risk control. One stakeholder stated that while there has been substantial work by industry on interventions, the results are mixed – “some work, some don’t.” He further commented, “The government needs more information before it considers factoring in interventions. For example, an intervention that works on chickens should not be assumed to work on turkeys. Likewise, interventions that work on small birds do not necessarily work on large birds. Industry should be required to have supporting documents with some kind of analysis showing the intervention works.”

Another stakeholder thinks that interventions are “the right idea,” but is skeptical that adequate characterization of the impact on risk can be accomplished and, therefore, inclusion of intervention is not “fruitful or defensible.”

Another stakeholder emphasized concern about incorrectly or unjustly penalizing small plants in calculating their risk profile because they have few or no interventions. He suggested that some small plants have very safe food safety production practices as a result of knowledgeable relationships with their suppliers and insure that they are not getting product that is contaminated. He further suggests that stressing quality of inputs can produce even better results than emphasizing the number of interventions at an establishment.

5. Data from Other Sources

Some stakeholders suggested that information from other sources should be integrated into the determination of establishment risk control. They want FSIS to recognize that multiple inputs and expertise outside of FSIS is needed in order for RBI to be successful. Some stakeholders emphasized inclusion of data gathered by establishments, including consumer complaint data, epidemiological data, microbiological testing data, and other information. Others emphasized the

importance of data collected by other entities, such as the CDC and state health agencies and even other programs within USDA. One person stated that current events have an impact on risk, and FSIS needs to consider and coordinate with others (e.g., when an animal disease is found, APHIS needs to be part of the conversation).

Those who support using industry data also suggested that, “this is an opportunity to encourage and to reward establishments who are committed to collection of data, e.g., environmental testing in RTE plants, and that are willing, under conditions that do not penalize them for vigorously searching for and eliminating pathogen harborages, to share that data with the Agency.”

C. Comments in Response to Specific Questions Posed at the Public Workshop

In small group discussions at the Public Workshop and in comments submitted electronically after the workshop, stakeholders responded to a series of specific questions related to ERC. In the summary below, it is important to note that most of the comments came from small group reports, with mixed groups of stakeholders. As such, it was not possible to differentiate which stakeholder group offered which comment.

In the presentation on ERC at the Public Workshop, the categories were different from those listed in the paper, *Measuring Establishment Risk Control for Risk-Based Inspection*. The categories under ERC presented and discussed at the Workshop are:

- System Design
- System Implementation
- Food Defense
- Enforcement Actions
- In-Commerce
- Pathogen Control

1. Are these six components appropriate and adequate?

Generally, stakeholders thought the six components were fairly appropriate, with the exception of one component. A substantial majority of stakeholders concurred that food defense should not be a component of the RBI model. While many stakeholders stated that food defense is important and should be examined, they strongly believed that food defense should not be a part of daily inspection activities and should be handled as part of other FSIS activities.

Some stakeholders also questioned the inclusion of enforcement actions, since establishments often adopt better food safety controls after an enforcement action is taken.

Stakeholders found it much more of a challenge to determine or discuss whether the components were “adequate.” They wanted much more detailed information about the components, their definition and what was included in each, and how they might be weighted (Question 2) before they could evaluate the individual and collective components’ appropriateness. For example, questions were raised about the definition of “in-commerce” and “interventions.” In addition, some stakeholders raised issues surrounding the qualifiers used to define consumer information. They wanted to know more about what is included in “verified and validated consumer complaints” and how this is defined. Stakeholders also raised questions about how the absence of information might

be taken

into account. For example, how will the lack of pathogen testing at some establishments be evaluated in determining and establishments risk control?

In addition, stakeholders wanted to know what data would be required within each of these components and whether adequate data are, or could be, collected to support each component. Several stakeholders commented that while they think these categories may make sense for assessing an establishment's risk control effectiveness, they are very concerned with the data quality undergirding each of these categories. They further commented that if the data do not accurately reflect the reality at each establishment, risk cannot be determined effectively. Some stakeholders believed that for different components, data quality varies.

Stakeholders were divided on how to categorize, standardize, and use qualitative data. Some stakeholders believe that if an algorithm is used to drive determination of risk, only quantitative information and data should be used. Others thought that the use and consideration of only quantitative data would not adequately capture a picture of an establishment's effectiveness in controlling risk.

Stakeholders suggested that some components could be combined, such as enforcement and in-commerce, or enforcement and design implementation.

Another group of industry stakeholders that submitted their comments electronically following the workshop suggested an alternative list of categories for determining establishment risk control:

- System Design
- System Implementation
- Intended Use of Product
- Process Interventions
- Pathogen Control

2. *Are some components more important than others, and thus should be weighted more than others?*

Stakeholders thought a variety of the components were very important and should have greater weight, but for the most part did not sort through or reach conclusions about the relative weight of different components. One work group from a remote site, however, did suggest that "All components are equally important in considering risk control and none should be weighted more than others." However, most stakeholders expressed a range of perspectives on their relative importance of components and how they should be weighted.

One group of stakeholders that participated in the Public Workshop remotely proposed the following ranking: 1) Pathogen control; 2) In-commerce findings (if they are related to food safety, e.g., serotypes for public health concern); 3) Enforcement actions; 4) System design; 5) System implementation; and 6) Food defense. Other suggestions included emphasizing pathogen control and system design – or pathogen control, system design, in-commerce, and food defense – as the most important. Another stakeholder who submitted extensive comments electronically strongly stressed pathogen control and associated pathogen testing results as the most critical factor in assessing and controlling risk. He advocated that pathogen testing is the only true and objective

indicator of whether or not and the degree to which microbiological hazards are present and therefore should be weighted the most heavily.

Several stakeholders saw system design and implementation as closely linked and felt they should drive the rest of the assessment of an establishment's ability to control risk. Many stakeholders commented that verification of design and implementation is critical, and plants' data must support the processes they use to produce food that is safe. They noted that verification requires more than "just looking at paper," and must involve in-plant presence and review.

The single component on which the majority of stakeholders agreed was food defense. Most Workshop participants agreed that food defense should be removed completely of, if kept in as a component, should be given minimal weight.

Stakeholders also commented on other components of ERC. Some highlighted in-commerce and pathogen control. Some underscored and even gave priority to findings for food-borne illness outbreaks or attribution data. Others discussed the need for clarity of definition and validation of interventions in order to weight them appropriately. Still others mentioned differences of scale among plants as a factor to be considered.

In the context of weighting components, many stakeholders raised the issue of data quality, both in terms of how data quality should influence weighting components, as well as whether adequate data currently is or could be collected, and the consequences of inadequate or poor data. Many stakeholders advocate for a "data-driven" system, but have very different ideas about how to accomplish this objective.

Stakeholders also discussed the need for flexibility in determining an establishment's risk control effectiveness and the need for a calculation of ERC that can incorporate new information in a timely manner. For example, establishments that produce a variety of products on a seasonal basis should be ranked differently and according to the risk controls in place appropriate to that period of production.

Stakeholders also discussed the appeals process for NRs in terms of when this information should be included in determining an establishment's ability to control risk, and whether unintended consequences could be detrimental to achieving better food-safety practices.

3. Is there other useful information about establishment risk control that FSIS is not considering?

Stakeholders responded to this question in a variety of ways. Some expressed general satisfaction with the comprehensiveness of the components proposed by FSIS. Other stakeholders suggested other or additional categories of information, sources of information, and other ideas, including:

- Consumer complaint data not directed to FSIS;
- Public health data or attribution data (e.g., data collected by state governments or the Centers for Disease Control and Prevention on a geographic basis);
- In-plant microbiological testing with 3rd party audits (if applicable);
- Implementation of Food Safety System, HACCP deviations, and SSOP deficiencies involving product and contamination;
- Intervention strategies;

- Quantification of pathogen numbers; and
- The “extras” an establishment is doing to go ‘above and beyond’ (i.e. environmental testing, HEPA filters, product flow).

4. *Are there other ways besides Food Safety Assessments (FSAs) to evaluate food safety system design?*

Stakeholders commented on FSAs as well as other ways to evaluate food safety system design. There were divergent views on the value of FSAs. Some stakeholders commented that the current FSA method is becoming very effective and, coupled with other information such as microbiological data, consumer complaints, food safety-related NRs, forms a fairly accurate picture of an establishment and whether control measures are working.

In contrast, other stakeholders think FSAs are not good measures of establishment risk, because they are expensive, inefficient, time consuming, do not accurately represent what is happening at an establishment, and may even discourage plants from adopting and implementing food-safety measures. Some suggested an alternative approach that focuses on validation of HACCP, which they thought would result in generating more information about the effectiveness of the establishment’s risk control efforts. Others suggested an approach that rewards plants that are implementing good food-safety practices, and requires those with poor sanitary practices to pay for the costs of any additional FSIS oversight.

Some stakeholders did note that, while not perfect, FSAs do represent information in-hand and can represent at least an initial picture of what is happening at the establishment. They further stated that data-only analysis is not adequate and, at some point in the evaluation of an establishment’s food safety system design and implementation, someone needs to go to the plant and look at what is happening. Other supplemental means of evaluating food safety systems design included: 1) PBIS data, including positive information, not just NRs; 2) company FSAs and third party audits, if applicable; and 3) information from local inspectors and inspection supervision and management.

5. *Are the NRs FSIS is considering public health related inclusive or are there others FSIS should be considering?*

Stakeholders voiced divergent views on whether and how NRs should be considered in determining ERC. Some stakeholders suggest that NRs should not be factored in at all because they are subjective information and, therefore, should not be added to a quantitative algorithm. Other stakeholders commented that while not perfect, NRs do represent data in-hand and are tools to help understand what is going on at different plants with regard to risk control. Another stakeholder commented that NRs should be carefully weighted on its merits, not just its regulatory reference.

Some stakeholders, understanding that FSIS’s preliminary cut at categories of NRs relevant to public health still needs more narrowing, suggest that a clear process is needed to further determine which NRs are health-related and which are not.

Other comments about NRs included ideas about the appeals process and whether or not to return to the “Major, Minor, Critical” system.

6. *What is an appropriate look-back window?*

Stakeholders responded to this question by interpreting “window” in a couple of ways: 1) as a set period of time that passes before new data are reviewed; and 2) as a moving window of time that determines the data set that is compiled and reviewed. Regardless of interpretation, stakeholders gravitated toward a six-month or one year time period.

Other comments focused on making sure that whatever period of time is used, it is adequate both to account for seasonality and other variations in production (i.e., shelf life), and to provide an adequate assessment and clear determination of the establishment’s control of risk. Some suggested using a baseline (i.e., one year) with adjustments as appropriate to incorporate production variations resulting from seasonal changes as well as technological or other process modifications and upgrades. Other suggested assigning greater weight to more recent data.

V. IMPLEMENTATION

During early formal discussions with stakeholders, a significant theme emerged – the lack of clarity on how FSIS intended to implement an RBI system both in terms of determining relative risk posed by different establishments and how this measure translates to “on-the-ground” inspection effort. In response, FSIS developed a presentation for the Public Workshop that captured its preliminary thinking on implementation with the intent of gathering feedback and additional information and insights from stakeholders. At the workshop, stakeholders were able to offer their initial reactions and ideas, and subsequently they shared additional thoughts in writing. The comments summarized below came from the Public Workshop and electronic communications submitted through the FSIS website.

A. Comments on Specific Aspects of Implementation

Some stakeholders felt the Agency had made progress toward their goal of implementation, but from many stakeholder comments during the Public Workshop, it is clear that there is substantial confusion and associated frustration surrounding FSIS’s plans to implement an RBI system for meat and poultry processing. Much of this confusion and frustration seems to stem from perceptions of a significant lack of detail, maturity, and clarity around major pieces of the proposed RBI system coupled with the sense of a rapidly approaching timeframe for implementation.

One consumer group asked that the Agency provide: 1) a document that defines “risk-based” and “more robust risk-based,” describes the purpose and goals of the proposed program, and an outline of the history and scope of the project; and 2) a legal memo outlining what statutory provisions justify the Agency’s actions, what regulatory tools the Agency intends to use to implement its new program (e.g., will it use rulemaking or seek to accomplish its goals by directive to inspectors), why it has chosen that course, and what other options it considered.

Industry representatives expressed concerns about the potential unintended consequences of a numerical ranking system, in particular that consumers or customers might question the safety of products produced by the lowest rated plants. They pointed out that regardless of the ranking or

number assigned to an establishment, meat and poultry products cannot bear the mark of inspection unless they have been deemed “wholesome and not adulterated” by the Agency. Due to these types of concerns about misinterpretation by the public, these stakeholders suggested that the numerical categorization of inspected establishments should not be subject to release under the Freedom of Information Act (FOIA).

1. Timeline for Implementation

In comments in early discussions, during the workshop, and in electronic communications, some stakeholders indicated that the timing for implementation of the RBI system should not be driven by FSIS budget demands or political interests, and that there may be negative consequences if FSIS rushes to implement a system that is still in the nascent stages of development. In response to the report in *Food Chemical News* that seemed to indicate FSIS plans to begin implementing RBI in the first quarter of 2007, consumer groups strongly emphasized that FSIS must slow the process down. Others, noting that the Agency has already begun the process of discussing implementation of RBI for poultry slaughter, contend it lacks the statutory authority to do so. One of these stakeholders suggested that instead of rushing to implement an RBI system, FSIS should set as a top priority the development of a state-of-the-art infrastructure capable of collecting and analyzing quality data relevant to determining both product risk and establishment risk.

Another consumer group suggested that FSIS develop a timeline that shows the Agency’s plan for implementation, data collection to support the plan, specific actions with regard to directives for its inspection force, dates for the completion of each major step, and the final plan. Also included in the timeline should be an indication of when and in what manner FSIS expects to provide opportunities for public comment and public participation.

Also, in connection with the pace of implementation, these stakeholders reiterated the importance of a transparent and inclusive process as FSIS moves to strengthen the proposed RBI system.

2. Pilot/Testing Phase

Many stakeholders recommended that the Agency test the proposed RBI model in a few areas (e.g., establishments, regions, or some other clusters) prior to implementing it across the country. In doing so, these stakeholders suggested FSIS could absorb lessons learned on a much smaller scale with a smaller impact on the public, address unintended ramifications, and obtain a better sense of what additional training or information is needed for inspection personnel and industry.

One group of stakeholders suggested that FSIS begin a multi-phase release by introducing the proposed RBI program at establishments with the lowest PIR and best ERC, and once proven successful there, expand to other establishments. To these stakeholders it seems reasonable to pilot the program in a single district or, alternatively, in various circuits within several different districts to give an overall indication of where adjustments need to be made before the program is implemented nationwide.

Another stakeholder suggested that ideally the Agency would perform a trial of the proposed RBI program side-by-side with the current PBIS system to compare the “risk-based inspection” model with the current inspection system, and gather data to support an overall shift to the new model.

3. Ongoing Adjustments/Flexibility

Several stakeholders from all different interest groups and points of view identified the need for FSIS to have the capacity to make ongoing adjustments in the proposed RBI system. Several stakeholders, particularly from industry and FSIS employees, emphasized that the final risk value assigned to an establishment must be an evolving number that is continually reevaluated as plants make improvements in their food safety systems, change their processes or products produced, or have findings by inspection personnel that warrant a new determination of their risk value. Others requested that the Agency identify whether and how an establishment's ranking can be changed and how often the ranking could change.

Some stakeholders pointed to the need to revisit the design of the RBI system periodically as pathogens mutate or other new pathogens emerge. They also suggested looking at pathogen-specific markers and whether they change over time.

Other stakeholders noted that periodic adjustments in the allocation of inspection resources may be needed to address the increased risk associated with the seasonal or regional factor(s), for example, to provide additional inspection presence in raw ground beef operations during the months of July and August, when data show increased numbers of *E. coli* O157:H7 illnesses associated with undercooked ground beef. In fall and winter months, when some production factors change (e.g., weather and water temperature become cooler, production volume of some products, like hot dogs, declines as demand and consumption decreases), an associated adjustment of resources also should be made.

Some stakeholders commented that, because so many plants make a wide variety of products and many are occasional, seasonal, or only periodically produced, it is essential to increase the flexibility of inspection data systems like PBIS, so inspection personnel can input specific production data that will generate sample requests when the product is actually being produced. These stakeholders emphasized the need to trust inspectors, who know the plant production systems, to schedule or to modify PBIS (or a new RBI system) as needed to reflect in real-time what the plant is actually producing and what tasks/sampling need to be completed related to that production.

4. Evaluation

Throughout the information gathering effort, every stakeholder group made recommendations about how FSIS should evaluate a proposed RBI system. Many stakeholders emphasized the importance of clearly documenting and supporting actions of the program so that stakeholders understand what is being done and how. One stakeholder stated that, "In the end, FSIS will have to tell us how they can have an effective program that can also turn back legal challenges that say the program is beyond their authority."

Verification of results is, "the million dollar question." Several stakeholders said FSIS must demonstrate reductions in food-borne illness rates, including reduction in particular pathogens such as *Salmonella* and *E. coli* O157:H7, *Lm* and others to be identified in the future. One stakeholder commented that documented targeted inspections over time would lead to achieving that goal. However, they also said that a reduction in rates will be hard to measure in the short term and suggested that the Agency needs to identify and use proxies, including internal (inspector) acceptance, external constituent acceptance, and success with identifying problems previously

missed by the PBIS system.

Some stakeholders want a very transparent evaluation process, including how a plant does or does not comply with each factor. Comparative assessment is needed and should be explicit when comparing plants with like processes.

The following is a list of measures for evaluating RBI suggested by stakeholders:

- Decrease in occurrence of food-borne illnesses attributable to meat and poultry products;
- Reduction in the prevalence of pathogens in the products themselves;
- Decrease in product recalls;
- Success in identifying problems previously not identified;
- Reduction in resources spent on non-food safety-related NRs, both by FSIS inspection staff and establishments during the initial issuance and the appeal process;
- Decrease (or increase) in number of food safety NRs, enforcement actions;
- Improvements in operations (e.g., lowered risk ranking) at establishments where inspection resources are increased;
- Increase in the consistency of FSIS inspection on an inspector-by-inspector basis and on an establishment basis;
- Ability to free up limited inspection resources from processing plants to be directed elsewhere, such as further along the distribution chain, while maintaining the current level of food safety;
- Decrease in number of plants that demonstrate continued food safety control under reduced inspection;
- Increased use of food safety interventions by establishments, reductions in microbial contamination of meat and poultry products, reduction of environmental *Listeria* in RTE plants, etc.;
- Internal FSIS stakeholder acceptance;
- External constituents acceptance; and
- Improvements in the appropriations bill.

One stakeholder pointed out that comparative assessments and other performance measures would be needed when comparing plants with like processes.

5. Inspection Work Force

Many stakeholders discussed the work force as a critical component for the successful implementation of risk-based inspection. Some stated that the current work force faces many challenges including chronic shortages, lack of authority to address problems in “real time,” political pressures, inadequate training, and low morale. Some stakeholders cited these problems as a weakness in the Agency’s proposals for a more risk-based inspection system.

a. Inspector Shortages

Several stakeholders emphasized a chronic problem of inspector shortages and the associated impact on deterrence of unsafe food safety practices. They expressed frustration that the Agency does not acknowledge this problem but instead continues to comment that inspectors are in “every plant every day.” This, they state, is impossible with the current levels of inspectors and the ongoing shortage is creating potential food safety problems, and the perceived indifference of the Agency’s

senior levels is negatively affecting inspector work force morale. However, others think the inspection process is moving in the right direction and emphasized that, “Throwing more inspectors at problems is absolutely the wrong thing to do.”

c. Inspector Authority

Authority of the inspection work force also was a topic of discussion with several stakeholders. Some saw authority as an issue fundamental to making RBI work in terms of applying appropriate attention where needed to maximize good food safety practices. Other stakeholders stated that inspectors in plants have to have ability and authority to do their own assessments and take actions. They further pressed this point by suggesting that inspectors in the plants are the ones who are observing what is going on and, given how quickly food safety issues can develop, they must have the ability and authority to respond. One stated, “Over and above any algorithm, have an inspection team override – give them the ability to make a determination that a plant needs more or less inspection based on what they know about that plant.”

One stakeholder proposed three dimensions of the work force (inspectors) that are necessary to ensure food safety and better protect public health: 1) In-plant presence of inspectors (to act as a deterrent); 2) Inspectors with actual authority to take action while they are there; and, 3) Increased microbial testing by inspectors. He stated that there has been an erosion of inspector authority, and the Agency has become less stringent with enforcing HACCP guidelines. He cited as an example that when many plants had problems with the policy for NRs for “fecal failures,” the Agency changed the standard. He also stated that historically, if inspectors found ten deficiencies for the same problem, they would write ten different NRs. Now, those ten deficiencies are written into one NR. He asserted that the Agency has used this declining number as a measure of improved food safety when, in fact, it is a change in inspection protocol and a decline in inspector authority.

This stakeholder also proposed increased microbial testing by inspectors. He said that the Agency has the authority to do this without additional regulatory action and that they should exercise this authority to increase efforts on *Lm* and *E. coli*, similar to their activities on *Salmonella*, and begin testing for *campylobacter* – for which inspectors currently do no testing.

Another person said that, “As the Agency implements this system, they will have to have a different type of inspector - more knowledgeable inspectors who can find a legitimate problem and who can be fair to companies. For example, without inspectors on every shift, companies will find ways to cut corners. So an inspector has to be able to do an assessment of what’s wrong, how serious the problem is, and the authority to do something about it,” including working with the company or taking or triggering enforcement action.

Some stakeholders asked questions about who, ultimately, has responsibility for determining risk at plants - those who are on-site or personnel off-site – and who will have what information.

c. Inspector Training

Several stakeholders commented on the importance of FSIS employee qualifications and training, including how critical good skills are to making the meat and poultry inspection process effective. They observed that plants with well-trained EIAOs would get more information and suggestions for how to address problems and improve their process and food safety. One person stated that,

“Training is extremely important and it should be science-based, not just explaining how to fill out the forms.” Another person commented that new employees involved with inspection of poultry currently receive less training and have a higher turnover rate than longer-term employees.

Other stakeholders commented about the importance of training to develop trust and cooperation among the team of inspectors. They related a recent situation in which, an inspector had disciplinary action (i.e., a two-day suspension) brought against him as a result of an FSA he had written. These stakeholders further stated that this type of disciplinary action used to happen fairly frequently, causing huge mistrust that is just beginning to be overcome. This recent event has sent a chill through the inspection force in that area, raising concerns among inspectors about being disciplined for just doing their jobs. These stakeholders believe that in order for RBI or any inspection system to work well, EIAOs and inspectors have to work as a team – they have to trust each other. They noted that there are other ways to deal with problem inspectors, such as performance reviews with supervisors, and extra training.

6. Education/Outreach

Several stakeholders emphasized the need for both the Agency and key stakeholders to reach out to industry establishments to take ownership of the idea of RBI and provide support where necessary under the new system. In particular, some of these stakeholders recommended FSIS assist plants who may have a higher associated risk, and provide more guidance for small and very small establishments related to the approved or accepted controls that may reduce their overall risk value. According to this group, this type of specific information may give establishments the incentive to incur the expenses necessary to reduce their associated risk.

Some stakeholders suggested that implementation of an RBI system will require a huge recruitment, training, and education effort – for both inspectors and those working in the establishments. One stakeholder suggested that FSIS remain open to recruitment of individuals without experience in the food industry. In his view, the current training programs are sufficient for anyone with the mathematical, reading, and writing aptitudes required to carry out the duties of inspection.

7. Implementation Alternatives

One industry group suggested FSIS consider, as an alternative to the quadrant matrix illustrating the relationship between the PIR and ERC, a continuum of plant ratings that incorporates all components of the two dimensional matrix, including PIR, ERC, production volume, and interventions. Although they see advantages to both approaches, these stakeholders think that placing establishments along the continuum may be easier to justify and lead to less disagreement.

Some stakeholders suggested that FSIS create, as an alternative to the proposed scoring system, four categories: 1) approved; 2) minor deficiency; 3) needs improvement (no business until remedied); and 4) deficiency (unacceptable system failure). One pointed out that this is similar to an old PBIS system for ranking problems as major, minor, or critical, and felt that, although there were problems with this system, it might be worth thinking about as a basis for the new system. Other stakeholders raised concerns about returning to a system like the “Minor, Major, Critical” of the past, stating that the enforcement efforts and use of FSAs are working quite well and can continue to be improved with the desired results of encouraging safer meat and poultry production practices and protecting public health. Some stakeholders suggested that a scoring system will require more inspection

resources (not fewer); and that a scoring system by itself is not as effective as industry audits because scores do not give details for where and how to make improvement. One stakeholder further commented that quality personnel and tools are needed more than just additional inspectors.

Another group of stakeholders suggested a system in which inspectors give a number to each item on a checklist of problems and then add up the numbers for a final rank. These stakeholders would also include a mechanism for incorporating the inspector's own sense of whether plants are problems or not.

8. Other Suggestions

Stakeholders offered several other suggestions for FSIS's consideration:

- Before implementation of RBI, have front line supervisors (FLS) and EIAOs visit all establishments and submit a report of the conditions of the establishment (but not conduct a full FSA);
- Consider not turning off the PBIS scheduler, but instead have the risk data control the scheduling of which tasks are most important from a food safety standpoint. This would improve uniformity across districts and from plant to plant;
- Take advantage of an electronic system and have inspectors conduct record review remotely instead of at the establishment;
- Use the USDA mark to create incentives for industry;
- Reward establishments that effectively, aggressively, and consistently conduct internal food safety education programs that result in improved execution of their food safety systems;
- Reward establishments that investigate and implement additional food safety interventions;
- Encourage firms to share internal data by establishing protocols that do not penalize firms for reporting positive findings for pathogens if they subsequently take steps to eliminate or minimize the problems; and
- Ensure that RBI is compatible with international expectations, so that implementation of a RBI system does not adversely affect international trade or the concept of equivalency with international trading partners. They also recommend that FSIS keep international trading partners informed about the development of a RBI inspection system.

B. Comments in Response to Specific Questions Posed at the Public Workshop

During the Public Workshop FSIS put forward a series of questions related to implementation. The stakeholders spent some time at the Workshop responding specifically to the following questions, and subsequently stakeholders some, both individually and from organizations, also shared comments in written form, submitted electronically.

1. How many levels of inspection are optimal?

Some stakeholders felt the five levels originally put forth by FSIS seemed too narrow to fully differentiate establishments. Instead, the suggestion was made to create nine levels of inspection. Others indicated that the meaning behind each level is more significant than the number of levels of inspection.

Stakeholders are very interested in the Agency's utilization of quantitative data in determining a particular establishment's level. They also want to have enough detail to gauge the overall impact of

this scoring system and whether it will, in fact, have the desired impact of improving food safety and how. In addition, these stakeholders recognize that the Agency's discussion papers and the issues on implementation presented are preliminary and will be subjected to further thought and consideration. But these stakeholders also feel that if the Agency approaches RBI through the use of algorithms or some other modeling technique, non-quantitative, subjective information should not overrule the values delivered by the model.

Many stakeholders from all interest groups voiced significant interest about: a) the details of how levels are assigned and what the array of establishments will be that are assigned to those levels; b) the inspection effort associated with each level; c) the requirements for establishments in different levels; d) the public perception of being assigned to a particular level; and other details. They raised a series of questions regarding inspection levels, which they felt needed to be addressed prior to implementation:

- Will low risk facilities have any inspectors?
- At what point will/does a high-risk facility become too risky? What criteria will the agency use to determine when a high-risk facility should be shut down? Will the Agency (and the proposed RBI system) put out of business those plants that chronically are not using safe food practices?
- How will processing facilities be ranked in order to differentiate a high-risk facility from an even higher risk facility?
- How will the time or number of visits be determined? By the number of NRs issued and products the firm produces?
- Will the FSAs conducted by the Enforcement, Investigations, and Analysis Officers (EIAO) be considered along with the enforcement actions taken against an establishment or the lack of appropriate actions?

Some stakeholders – particularly those from industry – made the point that an RBI system should result in a more efficient and appropriate use of resources to enhance food safety for consumers and not an additional layer of inspection.

2. How do plants move from one level to another?

Answers to this question linked to the next question regarding timeframe for reevaluation. Some stakeholders suggested establishments should move between levels based on data considered by FSIS either during the 6 month/1 year reevaluation period or in response to new information proffered by the establishment/generated by FSIS.

Also embodied in answers to this question was the concern about when the Agency would review data and other quantitative information, possibly through a “look back window.” For some, FSIS comments at the Public Workshop did not appear to contemplate the possibility of a transparent algorithm that could be corroborated by the plant, nor did they address incorporating extensive data that some facilities generate through their own testing regimens into the Agency's consideration. These stakeholders felt both options should be permitted.

3. How frequently should FSIS evaluate data to make decisions on the plant moving from one level to another?

This question also was raised during the small group deliberations on the ERC paper. Stakeholders suggested the period range from six months to no longer than a year. Some suggested the timeframe should be a moving window with an establishment being able to request that FSIS revisit or reassess the classification “for cause.”

Some stakeholders suggested that a six month to one year rolling “look back window” would provide an opportunity for an accurate assessment of an establishment. One group noted however that the normal frequency for recalculating an establishment’s risk ranking should be monthly. They proposed that the District Office would allocate resources based on this ranking. Further, if an establishment makes changes that would significantly affect its ranking (e.g., by adding a new intervention), then they should be able to request a recalculation incorporating the new information. Likewise, if the Agency takes enforcement action against an establishment, it may be appropriate to recalculate the risk ranking before the next regularly scheduled monthly reassessment and reallocate resources for the current period.

4. Should we use predictive indicators?

While this concept was brought up at the Public Workshop, it appeared to most stakeholders that more definition and information regarding the concept of “predictive indicators” would be needed to clarify what they are and how they would be used by inspection personnel in an RBI system.

From the examples given in the FSIS presentation, it appeared to some that predictive indicators are situations or events that would indicate that a higher level of inspection might be warranted. In response, some stakeholders felt that the way the establishment manages these situations or events should be key to the Agency’s reaction to such predictive indicators. These stakeholders suggested, for example, that if the establishment implements processes (such as special cleaning and sanitation or additional sampling and testing of the environment or products) in reaction to a situation or event, then enhanced inspection probably is not warranted. Further, in these stakeholders view, many of these issues could be managed in the weekly meeting or by proactive notification of the inspection staff by the establishment. They noted that this is an area where subjective interpretation of situations could lead to disagreements about the significance of a predictive indicator, and might provide a compelling reason for the Agency to be able to quantify a factor before considering it in the context of a RBI system.

Others noted that, as they understood it, predictive indicators address foreseeable but not consistent hazards. As such, these types of hazards should be considered in the establishment’s HACCP plan and would be covered in the system design component.

One industry group also provided in electronic communications answers to the following two questions:

a. How would we capture predictive indicators?

They suggested two means of capturing the information: 1) weekly meetings, and 2) proactive communication from the establishment to the inspection staff regarding special circumstances or events that could result in a predictive indicator situation. In all cases, they added, having a pre-determined list of examples of predictive indicators with objective measurement criteria would help facilitate communication between FSIS and establishments. If the establishment knows how a situation will be incorporated into the Agency's analysis, it could communicate relevant information to the inspection staff and document what the establishment is doing to monitor the situation and mitigate any possible adverse effects on food safety.

b. What are other examples of predictive indicators?

In addition to the examples provided by FSIS in the public meeting, this stakeholder group suggested the following possible predictive indicators:

- Change in cleaning and sanitation chemicals or procedures;
- Addition of new critical processing equipment;
- New operations management personnel in critical nodes; and
- Reassessed HACCP plans based on new CCPs or interventions.

5. What would be the recommended inspection activities for different inspection levels?

One industry group suggested using nine levels instead of five:

- Level 1: Electronic review of records; annual review of establishment self assessment on risk control (if applicable); review of establishment testing data in support of Level 1 ranking; annual review of HACCP reassessment; and FSSA conducted every 4 years.
- Levels 2-3: Electronic review of records; semi-annual review of establishment self assessment on risk control (if applicable); review of establishment testing data in support of respective Level ranking; annual review of HACCP reassessment; and FSSA conducted every 3 years.
- Levels 4-6: Electronic review of records; quarterly review of establishment self assessment on risk control (if applicable); review of establishment testing data in support of respective Level ranking; annual review of HACCP reassessment; and FSSA conducted every 2 years
- Levels 7-8: On-site review of records; monthly review of establishment self-assessment on risk control (if applicable); review of establishment environmental and product testing data; annual review of HACCP reassessment; and FSSA conducted every 2 years.
- Level 9: On-site review of records; weekly review of establishment self assessment on risk control, (if applicable); review of establishment environmental and product testing data; review of establishment raw material testing data; review of semi-annual sanitation audit by external auditor; semi-annual review of HACCP reassessment; and FSSA conducted annually.

Industry representatives also observed that FSIS would like recommendations for the types of inspection activities that minimally should be conducted at establishments that fall into each risk category. Some felt it might be premature to define these types of activities until there is a better-developed structure for ranking establishment risk. Nevertheless, in general, they suggested the focus should be on more intensive inspection activity for plants that are having trouble controlling their food safety risks.

VI. OPPORTUNITIES AND NEXT STEPS

When FSIS launched the RBI Initiative in 2004, stakeholder involvement was considered a key aspect of enhancing the ultimate design of and support for a more robust RBI system. FSIS has demonstrated interest in reaching out to its many stakeholders to assist in the development of the RBI system, by creating several means of soliciting stakeholder input on the various dimensions of RBI. Throughout the Stakeholder Input Process, we examined and contemplated stakeholders' comments and suggestions to glean insights about the ongoing development of the RBI system, the challenges in moving forward collectively, and opportunities that might lend themselves to additional stakeholder involvement. As the RESOLVE team collected substantive input on the scientific and technical aspects of RBI, we also paid close attention to *how* stakeholders conveyed their points of view, as that often revealed as much as *what* they said.

The information gathered between May and November 2006 offers a number of substantive suggestions for how to improve the RBI system, and could form the basis for determining how additional stakeholder input will be most fruitful as FSIS moves forward. The following information from the Stakeholder Input Process is important to consider in determining how additional stakeholder involvement will have the greatest merit:

- Substantive issues or dimensions of the design that could benefit from the insights of stakeholders with diverse expertise and perspectives;
- Stakeholder motivation to participate and contribute; and
- Productive and genuine avenues for stakeholder input.

The specific design and details of future stakeholder involvement is dependent upon too many uncertain variables, and is therefore beyond the scope of this report. There are, however, constructive steps that FSIS could take to build on work completed and information gathered through the Stakeholder Input Process, as well as other forums and activities. This section highlights a variety of considerations for contemplating future stakeholder input and offers some next steps for the FSIS as the Agency determines how stakeholder input could continue to enhance the design and implementation of a more robust risk-based meat and poultry processing system.

A. Substantive Topics for Continued Deliberation and Stakeholder Input

The two main components of RBI – PIR and ERC – were the focal topics of the Stakeholder Input Process. The changes between the Agency's description of PIR and ERC in the initial concept papers and later descriptions at the Public Workshop, demonstrated the influence that stakeholder input can and has had on the evolution of FSIS's thinking about RBI. This constructive interaction between the Agency and stakeholders points to additional opportunities for stakeholder involvement in the development of these components.

Many stakeholders voiced an interest in continuing to assist FSIS with the development of PIR and ERC to improve food safety and better protect public health. The Public Workshop and other information gathering activities illuminated several substantive topics of common interest among stakeholders that could be the basis of additional stakeholder involvement opportunities. For example, many stakeholders expressed interest in contributing input on the algorithm to determine how to use risk for determining the level of inspection activities at meat and poultry processing establishments. In addition to the further design of the components and the overall algorithm, the implementation of and transition to a RBI system is the subject of much stakeholder interest.

The topics listed below are of significant interest to many of the stakeholders. Almost all who have engaged in stakeholder input activities thus far have expressed interest in additional opportunities to help shape them and other aspects of a more robust RBI system. However, this list is not exhaustive, and it may not be necessary or desirable to involve stakeholders in sorting through and/or addressing every one of these topics or the myriad of sub-topics that could be listed under each.

Based on formal discussions, the Public Workshop, and comments submitted electronically, the RESOLVE team identified the following topics as potential areas for continued deliberation and stakeholder input:

- Further refinement of currently considered factors, such as NRs and FSAs;
- Whether and how additional factors will be included in assessing risk, such as volume, severity of illness, interventions;
- Whether and how data from non-Agency sources will be included, such as industry-generated data, attribution data collected by other government agencies, consumer complaint data outside of the Consumer Complaint Monitoring System, and other information;
- How PIR and ERC will be combined to determine an establishment's risk ranking, whether other factors or considerations (i.e. predictive indicators) will help determine ranking, and how specific rankings translate to the amount and type of inspection activity at respective establishments;
- How and why rankings might change, based on what, how frequently, and who decides; and,
- How and in what time frame implementation of and transition to an enhanced RBI system will be conducted.

B. Stakeholder Motivation

While stakeholders have expressed a broad range of views on various dimensions of the different components, including PIR and ERC, and preliminary thinking about implementation, there are strong common interests among stakeholders that indicate a positive foundation of stakeholder motivation to contribute to shaping a RBI system. Stakeholders view the meat and poultry inspection system, and modifications to it, through different lenses because of their diverse areas of expertise, their respective roles in or interests concerning meat and poultry processing, and how changes to the meat and poultry system might impact them personally and professionally. Though this diversity might seem daunting, it could also offer tremendous value if FSIS continues to tap into it as the Agency continues to develop, and then implement RBI.

In spite of the broad diversity of stakeholder perspectives on RBI, there are common themes that emerged during the Stakeholder Input Process and became more emphasized as the process

evolved. A foundation of common interests exists among stakeholders that would likely compel many to continue to provide input to FSIS if given the opportunity. Common interests include:

- Mutual recognition that improvements to the meat and poultry inspection process can and should be made;
- Risk should drive decisions about the best deployment of inspection resources to improve food safety and better protect the consuming public; and
- FSIS, as the Agency with authority over the meat and poultry inspection process, should succeed in enhancing the meat and poultry inspection process.

In our discussions with stakeholders, we also heard a wide range of hopes, concerns, and frustrations about RBI as a means of reallocating inspection effort, enhancing food safety, and better protecting public health. We also heard concerns about some aspects of how the RBI Initiative has unfolded. It is clear that stakeholders have very real and diverse points of view about:

- How to define the overall vision of the goals and objectives for best accomplishing improved inspection for meat and poultry processing;
- How to translate the concept of using risk to drive inspection resources into an actionable and successful program; and
- Fundamental differences between stakeholders as to what parameters (i.e., statutory and regulatory authority, level of resources, and/or data) are, or should be used, in designing and implementing a more robust RBI system.

It should be noted that some of these differences could discourage or even prevent some stakeholders from participating in additional stakeholder involvement opportunities, or supporting the approach to RBI that FSIS is proposing.

C. Genuine Opportunities

FSIS has provided and continues to provide multiple venues for stakeholder involvement, including but not limited to the Stakeholder Input Process on RBI and other related topics. Input from stakeholders suggests, however, that there is substantial confusion and concern about what real opportunities for stakeholder input exist. For example, the lack of an easily accessible, clear, and detailed description of FSIS's overall vision and substantive components of the proposed RBI system and the process for implementation of a new system has created concern about the design and value of established stakeholder input mechanisms and confusion on the overall RBI Initiative. The lack of this information is clearly due in part to the fact that this information is still in flux, but concern and confusion exist nonetheless.

Stakeholder enthusiasm for working together with FSIS in the future will depend upon genuine opportunities to provide input and the stakeholders' sense that the opportunities are authentic. If they are skeptical, and some already have expressed this skepticism, they might not participate constructively – or at all. The timeframe for implementation has been, and continues to be, unclear and stakeholders will become more anxious as they sense opportunities for input becoming more restricted. Thus, clarity about the Agency's vision and plans, and any stakeholder involvement processes will become even more critical as the time between design and implementation of RBI narrows.

D. Building on Work Completed and Next Steps

The challenges raised by stakeholder comments are many and significant. However, we believe that the foundation of common interests among stakeholders coupled with the continued evolution of RBI, can serve as a springboard for developing constructive and genuine opportunities for further stakeholder input. FSIS, in collaboration with the different stakeholders interested in and affected by meat and poultry inspection, has a significant opportunity to build on work conducted to date and further improve the design and implementation of a more robust RBI system.

Clarity and transparency are essential for maximizing the value of stakeholder input, both from work already accomplished as well as future activities. All parties could achieve much greater clarity if the Agency developed a comprehensive outline of the work it has conducted, and continues to conduct, including the types of information gathered, how it was reviewed, and how the Agency integrated it into the evolving design and implementation of the RBI system.

FSIS should also outline how and when the Agency will use future stakeholder input in shaping and implementing an enhanced risk-based inspection for meat and poultry processing and an overall improved RBI system. Such a roadmap should include the following details:

- Substantive topics to be the focus of stakeholder input;
- Description of which mechanisms (i.e. advisory committees, consulting sessions, technical workshops, etc.) will be used to solicit input on what topics;
- Time frame for the overall process and when stakeholder input mechanisms will be used; and
- To the degree possible, how the collected information will be reviewed and integrated.

Although such a roadmap would inevitably evolve with ongoing stakeholder input, and changes in FSIS thinking about the design of the RBI system, providing this information in an easily accessible, clear, and comprehensive format could help create much greater understanding of how FSIS is tapping stakeholder input to enhance the design of and support for an enhanced RBI system.

APPENDIX A - STATEMENT OF WORK

STAKEHOLDER INPUT FOR RISK-BASED INSPECTION

1. BACKGROUND AND OBJECTIVES

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS recently announced that it is in the conceptual phase of an initiative to make its meat and poultry inspection system more risk-based in order to better protect the consuming public. In the coming months, the Agency will be developing specific ideas about how to measure risk in federally-inspected meat and poultry establishments and how to vary how we inspect establishments based on risk. FSIS believes that its own employees, meat and poultry consumers, meat and poultry producers, state inspection agencies, public health groups, and possibly other stakeholders have an interest in—and valuable ideas about—how the Agency implements Risk-Based Inspection (RBI).

The purpose of this Task Order is to solicit 3rd party support in obtaining stakeholder input on RBI. The Contractor is expected to design methods and means to obtain input from stakeholders.

2. DESCRIPTION OF WORK

The Contractor shall conduct the following major tasks:

Task 1. Plan & conduct a Public Meeting on RBI

Public Meeting: The Contractor shall plan and conduct one public meeting on **October 10-11** to solicit comment from a variety of stakeholders, including but not necessarily limited to:

- FSIS employees,
- consumers and consumer groups,
- business owners/operators and industry groups, including food service and retail,
- public health groups,
- academic, and
- State inspection programs.

Attachment 1 of this Statement of Work presents a partial list of specific stakeholder groups that should at least be considered for inclusion in this study. The 3rd party will not necessarily be expected to solicit input from all of the specific groups listed in Attachment 2, but neither should

the 3rd party be confined to considering only the groups on this list. The most important consideration is that all groups have equal opportunity to participate.

The Contractor shall work with the Agency to identify problem areas in regard to RBI. The Agency will provide a listing of specific names and stakeholder contact information for utilization in the identification process. The Contractor will hold informal discussions with selected stakeholders. These discussions will allow the stakeholder to provide thoughts, concerns, and input on topics of interest to them. In any event, the Contractor shall not exceed 85 hours for this purpose.

FSIS Working Documents: The Agency has multiple areas in which it believes improvements could be made to further implement a more robust risk-based inspection system, such as better use of data and changes to inspection. In order to ensure that all interested parties have an opportunity to provide input on ideas that the Agency is considering, FSIS will provide the Contractor with draft working documents that explain the Agency's plans for RBI. The Contractor will use those documents, as well as meetings with FSIS, as a basis for preparing focus group moderators guides, slide presentations and handouts for public meetings, and other similar materials.

Webcasting: The Contractor shall arrange for web casting of the public meeting to other locations around the country. FSIS estimates the need for 50 ports for 8 hours. The Agency will provide equipment for video as well as staff to work it.

Consulting Group: FSIS works closely with the National Advisory Committee on Meat and Poultry Inspection (NACMPI). This Committee represents major categories of Agency stakeholders and regularly meets with the Agency to provide advice and recommendations on issues of critical importance to FSIS. There is an existing subcommittee of the NACMPI. The Agency will work with the Contractor on appropriate ways that the Contractor might be able to utilize this group. The Contractor will meet with the NACMPI by conference calls as needed up to four hours in preparation for the public meeting and NACMPI meeting in October 2006.

Task 2. Establish an Opportunity for Stakeholder Input Electronically

FSIS will also provide an opportunity for stakeholders to provide their ideas and information electronically. The Agency website will be the primary vehicle to assist in this effort and comments from the site will be provided as soon as possible to the Contractor. Information collected as part of this electronic vehicle will be incorporated into any summaries of stakeholder input provided to the FSIS. The Contractor will develop appropriate materials for the website to elicit stakeholder feedback.

Task 3. Synthesize Stakeholder Input and Report Important Findings to FSIS

The Contractor shall review, synthesize, and summarize its findings of its stakeholder information collection efforts. The findings should identify areas of stakeholder consensus about RBI, compare and contrast competing options about how to implement RBI, and highlight areas of concern among stakeholders regarding various options. Findings shall be presented in a variety of ways to facilitate understanding of all input.

Task 4. FSIS Interaction, Progress Reports, and Key Deliverables

The Contractor shall meet regularly with FSIS, submit monthly progress reports, and report key findings and recommendations to the Agency at prescribed milestones.

The COR will meet initially with the Contractor to discuss the project, provide the Contractor with important documents pertaining to RBI, arrange interviews with members of the RBI steering committee and Management Council, and introduce the Contractor to members of the NACMPI.

The Contractor shall review RBI concept papers, conduct interviews with Agency management and planning officials, and conduct interviews with several members of NACMPI to get possible stakeholder perspectives on RBI. The interviews with Agency personnel are to be in-person in Washington, DC. Interviews with NACMPI members may be conducted by telephone. The overall purpose is to facilitate the Contractor's preparation of an RBI public meeting.

The Contractor shall also attend the October 12-13 meeting of the NACMPI as follow-up to the public meeting.

In addition, FSIS will assist the Contractor in arranging one day, onsite plant visits in proximity to team members residence. These site visits are intended to help the Contractor get a better understanding of the plant environment where RBI will be implemented.

The Contractor shall submit a work plan consistent with Table 1 and be specific as to the conduct of the public meeting including:

- Preliminary interviews with COR, RBI Steering Committee, other FSIS Officials, and stakeholders in preparation for the public meeting;
- Site visits necessary for orientation of Contractor staff.;
- Proposed location and tentative date of the public meeting;
- Expected number of participants (e.g. consumers, industry representatives) in each session;
- Approach to engaging stakeholders in the meeting and soliciting input;
- Draft Public Meeting materials and report outline for agency review; and
- Other milestones the Contractor feels are pertinent.

Table 1. DELIVERABLES AND DELIVERY SCHEDULE

Offerors shall adhere to the following schedule and deliverable requirements.

Item No.	Description	Due Date	No. of Copies	Format/ Addressee
From Date of Contract Award				
1	Planning meeting with FSIS	May 24, 2006	NA	In Person/Washington DC
2	Draft Work plan that specifies interim and final products throughout the project	June 7, 2006	(3) Electronic (Word) and presentation in Washington DC	Electronic (Microsoft Word) and in person/CO and COR
3	Revised-Final Work plan	Within 2 week of receipt of comments on draft work plan	(3) Electronic (Word)	Electronic (Microsoft Word)/ CO and COR
From Date of Agency Acceptance of the Final Work Plan				
4	Meeting Materials- Draft to Agency	August 9, 2006	(3) Electronic (Word)	Electronic (Microsoft Word)/ CO and COR
5	Proposed report outline	September 20, 2006	(3) Electronic (Word)	Electronic (Microsoft Word)/ CO and COR
6	Hold Public Meeting	October 10-11, 2006	(3) Electronic (Word)	Electronic (Microsoft Word)/ CO and COR
7	Summary and recommendations report of Stakeholder Comments (DRAFT Final Report)	November 17, 2006	(3) Electronic (Word)	Electronic (Microsoft Word)/ CO and COR
8	Revised Final Report	December 1, 2006	(3) Electronic (Word)	Electronic (Microsoft Word)/ CO and COR

**[END OF STATEMENT OF WORK]
[Attachment 1 Follows on Next Page]**

Attachment 1 Stakeholders

Note: This list of stakeholders from whom input might be solicited by the 3rd party is provided as an example. It is not intended to be comprehensive. The 3rd party shall work with FSIS to use this list, and other sources, to identify and select stakeholders for actual involvement in the project.

FSIS Employees

- In-plant inspection program personnel (including bargaining unit employees)
- Front-Line Supervisors
- District Office personnel
- Technical Service Center staff
- Laboratory staffs
- Headquarters personnel

Consumers

- consumers and consumer groups
- Safe Tables Our Priority
- Center for Science in the Public Interest
- American Association of Retired Persons
- Consumer Federation of America
- Consumer Union of the United States
- Food and Water Watch

Industry

- American Meat Institute
- National Chicken Council
- American Association of Meat Processors
- National Turkey Federation
- National Meat Association
- North American Meat Processors
- Eastern Meat Packers Association
- Southeast Meat Association
- Southwest Meat Association

Public Health Agencies and Organizations

- Centers for Disease Control and Prevention
- Food and Drug Administration
- Animal and Plant Health Inspection Service
- Association of Food and Drug Officials
- National Association of State Meat and Food Inspection Directors
- Association of State and Territorial Health Officials

- Council of State and Territorial Epidemiologists
- National Association of County and City Health Officials
- American Public Health Association

Academic/Food Safety Consortia

- Extension Service at all levels
- Any University with interest in food safety and food security such as:
 - Auburn University: Detection and Food Safety Center
 - Illinois Institute of Technology: National Center for Food Safety and Technology
 - Iowa State University, Kansas State University, University of Arkansas: Food Safety Consortium
 - Iowa State University: Food Safety Project
 - Kansas State University: Food Science Institute
 - Michigan State University: Institute for Food Laws & Regulations
 - Michigan State University: National Food Safety and Toxicology Center
 - North Carolina State University: North Carolina Alliance for Food Safety
 - North Dakota State University: Great Plains Institute of Food Safety
 - Penn State University: Food Safety Programs
 - Purdue University: Center for Food Safety Engineering
 - Texas A & M University Institute of Food Science and Engineering: Center for Food Safety
 - University of California, Davis: FoodSafe Program
 - University of California, Davis: Western Institute for Food Safety and Security
 - University of Georgia: Center for Food Safety
 - University of Guelph: Canadian Research Institute for Food Safety
 - University of Maryland/FDA: Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
 - University of Minnesota: Center for Animal Health and Food Safety
 - University of Nebraska—Lincoln: Food Safety, Cooperative Extension Service
 - University of Tennessee: Food Safety Center for Excellence
 - University of Wisconsin—Madison: Food Research Institute
 - Virginia Tech: Center for Food and Nutrition Policy (CFNP)

APPENDIX B - ACTIVITIES TO DEVELOP A KNOWLEDGE BASE

Review of Background Materials

The RESOLVE team reviewed a variety of background materials to become familiar with the nation's current meat and poultry inspection procedures (i.e. HACCP), key events in the recent history of U.S. food safety (i.e. Supreme Beef Case), and the ideas outlined by FSIS in the first two RBI concept papers. Members of the RESOLVE team reviewed background materials including, but not limited to, the following:

- *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Proposed Rule* (USDA, FSIS; 2/3/95)
- *Guidebook for the Preparation of HACCP Plans* (USDA, FSIS; 9/99)
- *Meat and Poultry Inspection Issues* (Congressional Research Service; 6/6/03)
- *Food Safety Updated: Developing Tools for a More Science- and Risk-Based Approach* (Resources for the Future; 2003)
- *Scientific Criteria to Ensure Safe Food* (National Academy of Science; 2003);
- *Fulfilling the Vision: Initiatives in Protecting Public Health* (FSIS, USDA; 7/04);
- *Industry Perspective on Risk-Based Inspection, Its Components and its Execution by Industry and Regulatory Authorities* (Food Products Association; 12/2/05)
- Papers about RBI developed for the November 15-16, 2005 NACMPI meeting, and stakeholder comments related to that meeting.
- *FSIS Quarterly Report, Quarter 1, FY 2006* (USDA, FSIS)
- *Supporting Documentation Materials for HACCP Decisions* (Department of Animal Sciences and Food Science and Technology, The Ohio State University; 2/06)
- *FSIS Directive 5000.1 Revision 2: Verifying an Establishment's Food Safety System* (FSIS; 6/1/06)
- *RBI Primer Presentation* (FSIS; 2006)
- *Measuring Product Inherent Risk for Risk-Based Inspection* (FSIS; 7/06)
- *Measuring Establishment Risk Control for Risk-Based Inspection* (FSIS; 7/06)
- *Audit Report: Review of Pathogen Reduction Enforcement Program Sampling Procedures* (USDA, OIG; 9/06)

Orientation Meetings

Members of the RESOLVE team attended multiple meetings at the outset of their work with FSIS to help familiarize them with key stakeholder groups and representatives, and their perspectives on current issues in the food safety arena. RESOLVE team members observed the May 23-24, 2006 NACMPI plenary meeting, and sat in on the NACMPI RBI Subcommittee session at that meeting. They also met with the FSIS RBI Steering Committee to develop a knowledge base about the views of FSIS leadership on the Agency's move toward RBI. RESOLVE team members observed a joint consumer-industry meeting with Dr. Richard Raymond on May, 30 2006. Two members of the team attended a briefing by the Food Safety Research Consortium in Washington, DC on June 14, 2006 entitled "Improving the Food Safety Information Infrastructure." The briefing featured presentations about ongoing work to develop an enhanced food safety data infrastructure to support RBI.

Site Visits

RESOLVE T\ team members conducted a total of 11 site visits to meat and poultry slaughter and processing establishments of various types and sizes. Abby Dilley visited establishments in Michigan and Paul De Morgan visited sites in the vicinity of Portland, Oregon. Kathy Grant and Brad Spangler visited sites around the DC metropolitan area. At each site, RESOLVE team members met and were guided through the establishments by an FSIS inspector, EIAO Officer, or veterinarian. Inspectors identified the critical control points (CCPs) in the establishments and answered team members' questions about food safety inspection procedures. Collectively, the Team observed the following establishments first hand:

- Allen Family Foods, Cordova, MD – large poultry (chicken) slaughter and processing plant (7/31/06);
- J.W. Treuth & Sons, Baltimore, MD – small cattle slaughter plant with simple processing activity (8/2/06);
- Dietz & Watson, Inc., Baltimore, MD – medium size processing operation producing RTE products including lunch meats (8/2/06);
- Pacific Coast Fruit Company, Portland, OR – small RTE plant producing salads with meat on top (8/9/06);
- Willamette Valley Meat Company, Portland, OR – small meat and poultry processing plant (8/9/06);
- Harry's Fresh Foods, Portland, OR – medium size RTE plant producing soups and packaged foods (8/9/06);
- Fulton Meats, Portland, OR – small beef processing plant (8/9/06);
- Michigan Turkey Producers, Grand Rapids, Michigan – a medium size slaughter and RTE operation in two different buildings (7/24/06);
- Kent Quality Foods – small to medium RTE plant (7/24/06);
- Stehouwer's Frozen Foods – small raw cut and ground meat facility (7/24/06).

APPENDIX C -METHODOLOGY FOR THE STAKEHOLDER INPUT PROCESS

Stakeholder Database

To begin the process of identifying individuals and groups with whom to hold in-depth discussions, RESOLVE developed a database of the names and contact information of more than 250 stakeholders. RESOLVE gathered stakeholder names through consultations with FSIS, NACMPI members, and some key stakeholders identified early in the convening process.

Discussions with Stakeholders

RESOLVE coded the stakeholder database by interest group or sector and worked with the FSIS to identify approximately 45 key stakeholders with whom to speak. Key stakeholders are individuals who are likely and able to represent the interests of a broader constituency of stakeholders. The interest groups/sectors from which key stakeholders were selected included:

- FSIS employees;
- Consumer groups;
- Business owners/operators including processing plants, retail, and food service
- Industry associations
- Employees of processing plants;
- Public health groups;
- Other Federal, state, and local inspection agencies; and
- Academic experts in food safety, risk analysis, and data systems
- Other public interest groups.

See Appendix C.1 for a complete list of key stakeholders with whom we held discussions.

RESOLVE contacted and scheduled discussions with selected key stakeholders. The discussions each took approximately 60 to 90 minutes. Most were conducted by phone, while some were held in person. The discussions covered stakeholders' general thoughts and perspectives on RBI, their reactions to the Product Inherent Risk and Establishment Risk Control concept papers developed by FSIS staff, and their feedback about the stakeholder input process. RESOLVE primed stakeholders for the discussions with an introductory memo that explained the purpose and topics for the discussion, and RESOLVE's role as the facilitator of the stakeholder input process. See Appendix C.2 for Stakeholder Discussion Primer.

The information gathered from the discussions with stakeholders assisted RESOLVE in providing feedback to FSIS on the ideas outlined in the two concept papers; designing the public workshop portion of the stakeholder input process; and developing this report to FSIS. The RESOLVE Team compiled, reviewed, and analyzed the comments and ideas generated through the stakeholder discussions, organized them by topic and/or theme and integrated them into this report. RESOLVE shared general themes from the stakeholder discussions with FSIS staff periodically during the course of the process, but did not attribute statements to specific individuals. Nor will statements be attributed to individuals in this report.

RBI Public Workshop

RESOLVE collected a large amount of stakeholder input at the RBI Public Workshop hosted by FSIS, and held at George Mason University (GMU) in Arlington, VA on October 10-11, 2006. RESOLVE developed the agenda for the meeting, arranged and coordinated a webcast of the proceedings, and facilitated the workshop. RESOLVE designed the RBI workshop agenda in consultation with FSIS, drawing heavily on input gathered through RESOLVE's discussions with stakeholders. The key topics for the workshop were FSIS's vision for RBI, the key components of RBI, and implementation of RBI. The goals and desired outcomes for the workshop were:

Goals:

- Provide an overview of FSIS's vision for RBI;
- Discuss and gather input on key components of a successful RBI system; and
- Discuss implementation of and transition to these RBI components.

Desired Outcomes:

- Enhanced understanding of the vision for RBI;
- Ideas and suggestions for the key components of the RBI system; and
- Preliminary sense of implementation ideas, suggestions, and areas for additional work and discussion.

Please see Appendix C.3 for the complete Public Workshop agenda.

A total of 344 people participated in the October 2006 RBI Workshop: 145 people participated in the meeting on-site at GMU, and 199 people participated through the webcast (remote participants). See Appendix C.4 for the attendance/participation numbers by location. At GMU, participants provided input through questions and comments about FSIS presentations during plenary sessions, as well as small group discussions focused on the PIR and ERC concept papers. All 15 FSIS District Offices in the U.S., the FSIS Technical Service Center, the FSIS Center for Learning, and seven establishments served as host sites for remote participants. Remote participants listened to the proceedings and viewed presentation slides over the Internet for half of the proceedings on October 10, and all day on October 11. During the webcast portions of the workshop, remote participants submitted questions and comments via email, which RESOLVE compiled and organized. At points during workshop the discussion sessions at GMU, RESOLVE Team members stated questions and comments from remote participants, on their behalf.

FSIS and RESOLVE also encouraged remote participants to conduct small group discussions in parallel with the small group discussions happening at GMU on the afternoon of October 10. To help facilitate the remote small groups, RESOLVE developed a memo outlining some facilitation advice and the small group discussion questions, which FSIS then provided to the remote site hosts. Not all remote sites conducted small group discussions. Those that did provided their small group reports to RESOLVE and/or FSIS by email.

The RESOLVE Team compiled, reviewed, and analyzed the comments and ideas generated on site at the public workshop as well as by remote participants, organizing them by topic and/or theme for integration into the final report. Subsequent to the workshop, FSIS received questions and comments from participants and interested parties through the Federal Register and the Agency's RBI web page through October 27, 2006.

Electronic Input

The RESOLVE Team consulted with FSIS about options for setting up a web-based mechanism for interested stakeholders to provide input to the Agency electronically. FSIS established a page on its website that outlined the Agency's key questions on product inherent risk and establishment risk control and provided an email address for stakeholders to submit replies, questions, and comments (riskbasedinspection@fsis.usda.gov). FSIS staff agreed to forward all electronic submittals to RESOLVE so that the Team could track and compile questions and comments.

Prior to the public workshop RESOLVE received very few comments through electronic input. Workshop participants were instructed to provide follow-up comments on the workshop via the email address. After the conclusion of the 2-day RBI public workshop, RESOLVE compiled and organized approximately 35 electronic submittals. See Appendix C.5 for a listing of the individuals and organizations that make electronic submittals. The RESOLVE Team compiled, reviewed, and analyzed these questions and comments, organizing them by topic and/or theme for integration into the final report. The input received electronically is not highlighted in an independent section of this report; instead it is incorporated with all other input gathered throughout the process.

C.1: List of Key Stakeholder Discussions

FSIS Employees

Group Discussion:

- Michael Mayer, Association of Technical and Supervisory Professionals
- Chris Batcher, National Association of Federal Veterinarians
- Stan Painter, National Joint Council of Food Inspection Locals

Group Discussion:

- Richard Mackey, FSIS Supervisory Staff
- Rebecca Hairgrove, FSIS Supervisory Staff

Group Discussion:

- Linda Kendrick, FSIS Non-Supervisory Staff
- Corliss Green-Dixon, FSIS Non-Supervisory Staff
- Jeff Barham, FSIS Non-Supervisory Staff

Consumer Groups

Group Discussion:

- Caroline Smith DeWaal, Center for Science in the Public Interest
- Carol Tucker Foreman, Consumers Federation of America

Group Discussion:

- Nancy Donley, Safe Tables Our Priority
- Barbara Kowalyck, Safe Tables Our Priority

Group Discussion:

- Tony Corbo, Food and Water Watch
- Felicia Nestor, Food and Water Watch

Business Owners/Operators (including processing plants, retail, and food service) and Industry Associations

Group Discussion:

- Steve Krut, American Association of Meat Producers
- Ann Rasor, North American Meat Processors Association
- Hugh Tyler, The Butcher Shop

Group Discussion:

- Dick Crawford, McDonald's
- Dane Bernard, Keystone

Group Discussion:

- Craig Henry, Food Products Association
- Mark Dopp, American Meat Institute

- Bill Sveum, Kraft
- Craig Henry, Food Products Association
- Mark Dopp, American Meat Institute
- Alice Johnson, National Turkey Federation
- Rosemary Mucklow, National Meat Association

Public Health Groups

Group Discussion:

- Alan Baker, American Public Health Association
- Charlene Bruce, Association of Food and Drug Officials

Other Federal (e.g., FDA), State and Local Inspection Agencies

Group Discussion:

- J. Carlton Courter, National Association of State Directors of Agriculture
- Mike Mammings, Iowa Meat and Poultry Bureau Chief
- Carol Olhmstead, Association of State Meat Inspection Programs
- Steve Wells, North Carolina State Inspection Director

- David Horowitz, Food and Drug Administration, ORA
- Robert Tauxe, Centers for Disease Control
- Marlene Evans, OIG

Academic Experts in Food Safety, Risk Analysis, and Data Systems

- Mike Doyle, University of Georgia
- Fred Shank, Executive, Institute of Food Technologists
- Glen Morris, University of Maryland
- Michael Taylor, University of Maryland
- Elsa Murano, Texas A & M

C.2: Stakeholder Discussion Primer

Implementing a More Robust Risk-Based Inspection System

Background and Purpose of Discussion

The Food Safety and Inspection Service (FSIS) of the Department of Agriculture, the public health agency in the U.S. responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, is currently in the conceptual phase of an initiative to make its meat and poultry inspection system more risk-based in order to better protect the consuming public. This initiative is the next step in FSIS's plan to modernize the food-safety system begun nearly a decade ago, when the agency finalized its rules establishing HACCP (Hazard Analysis and Critical Control Points) systems in meat and poultry plants.

To move this initiative forward, FSIS has developed two papers regarding: 1) how to measure risk in federally-inspected meat and poultry establishments; and 2) how to vary how establishments are inspected based on risk. FSIS believes that its own employees, meat and poultry consumers, meat and poultry producers, state inspection agencies, public health groups, and other stakeholders have an interest in – and valuable ideas about – how the Agency implements risk-based inspection (RBI). To that end, FSIS has secured the services of RESOLVE to assist with the stakeholder input process.

RESOLVE is a non-profit organization specializing in helping people work productively, cooperatively and collaboratively together. RESOLVE is working with FSIS to gather stakeholder input on how to implement a more robust RBI system. In this initial phase, taking place over the course of the next several months, RESOLVE is holding in-depth discussions with a representative set of stakeholders; assisting with the establishment of a web page (on FSIS's website) to enable stakeholders and the interested public to provide comments; and planning and conducting a workshop open to the public to launch the process.

RESOLVE staff will be talking to a broad cross-section of stakeholders interested in and affected by meat and poultry inspection, including those representing FSIS employees; consumer groups; business owners/operators and industry groups; employees of processing plants; public health groups; other Federal, state, and local inspection agencies; academic expertise in food safety and risk analysts and data systems; and Congress. The discussions are expected to take approximately one hour. The primary purposes of these discussions are to:

- Obtain insight into risk-based inspection generally
- Gather feedback on two papers developed by FSIS, including:
 - Measuring Product Inherent Risk for Risk-Based Inspection
 - Measuring Establishment Risk Control for Risk-Based Inspection
- Collect ideas regarding the overall stakeholder input process

The information gathered from the discussions will assist us in:

- 1) Providing feedback to FSIS on the two papers and the ideas they contain;

- 2) Designing the public workshop portion of the stakeholder input process; and
- 3) Providing substance for the report RESOLVE will develop and submit to FSIS that will
 - o Identify areas of stakeholder agreement/disagreement about RBI;
 - o Compare and contrast competing options about how to implement RBI;
 - o Highlight areas of concern among stakeholders regarding various options; and
 - o Present recommendations for next steps in the stakeholder input process.

The discussions are confidential. While we plan to capture ideas, questions, concerns, and other relevant information in our report we will not attribute specific comments to any one individual.

Topics for Discussion

The following is a list of topics and talking points that will form the basis of the discussion. In the course of the discussions, other relevant issues may be raised and discussed.

1. Defining Risk-Based Inspection

2. FSIS Papers

Measuring Product Inherent Risk for Risk-Based Inspection

- Strengths of the ideas put forth
- Weaknesses and/or suggestions for improvement
- Considering inherent risk in implementing a more robust RBI system
- Ideas for determining or evaluating inherent risk

Measuring Establishment Risk Control for Risk-Based Inspection

- Strengths of the ideas put forth
- Weaknesses and/or suggestions for improvement
- Considering measurement of establishment risk control in implementing a more robust RBI system
- Ideas for determining or evaluating inherent risk

3. Implementing Risk-Based Inspection

- Other variables or factors that need to be addressed in implementing a more robust RBI system
- Measuring success of any new initiative or effort to implement a more robust RBI system

4. Stakeholder Input Process

- Goals for the overall stakeholder input process
- Goals for the public workshop and ways to accomplish them
- People or organizations/companies to involve in the process

C.3: Public Workshop Agenda

Risk-Based Inspection (RBI) Public Workshop

Hosted by:

Food Safety and Inspection Service (FSIS)

October 10-11, 2006

George Mason University
School of Public Policy, Arlington Original Building, Room 244
3401 Fairfax Drive
Arlington, Virginia 22201

AGENDA

Workshop Goals:

- Provide an overview of FSIS's vision for RBI;
- Discuss and gather input on key components of a successful RBI system; and
- Discuss implementation of and transition to these RBI components.

Desired Outcomes:

- Enhanced understanding of the vision for RBI;
- Ideas and suggestions for the key components of the RBI system; and
- Preliminary sense of implementation ideas, suggestions, and areas for additional work and discussion.

Proposed Ground Rules:

- Stay in one conversation
- Adhere to the agenda
- Be respectful - disagree without being disagreeable

Tuesday, October 10

9:30 – 9:50 am Welcome, Introductions, Workshop Goals and Outcomes

Dr. Barbara Masters, Administrator, FSIS

Dr. Richard Raymond, Under Secretary of Food Safety, USDA

Facilitator, RESOLVE

9:50 – 10:00 Workshop Ground Rules and Agenda Review

Facilitator, RESOLVE

- Review meeting protocols and logistics for fostering a functional and productive meeting; and
- Explain how the agenda builds toward the meeting goals and outcomes

- 10:00 – 10:30** **Presentation: Vision for Risk-Based Inspection**
Dr. Barbara Masters, Administrator, FSIS
Dr. Richard Raymond, Under Secretary of Food Safety, USDA
- Overview presentation on:
 - Key attributes of the envisioned RBI system;
 - Key components of the envisioned RBI system;
 - Establishment Risk Control
 - Determination of Product Inherent Risk
 - Using Risk to Direct In-Plant Inspection Activities in Processing Assignments
 - How the key components will achieve the vision
- 10:30 – 11:00** **Group Discussion: Vision for Risk-Based Inspection**
Facilitator, RESOLVE
- Facilitated group discussion about the vision for RBI
- 11:00 – 11:15** **Break**
- 11:15 – 12:15 pm** **Presentation: Product Inherent Risk**
Matthew Michael, Director, Program Evaluation and Improvement Staff, OPEER, FSIS
- Presentation on overall concept and key features of product inherent risk, and questions for group input (*45 minutes*)
 - Facilitated group discussion (*15 minutes*)
- 12:15 – 1:15** **Presentation: Establishment Risk Control**
Donald Anderson, Staff Officer, Program Evaluation and Improvement Staff, OPEER, FSIS
- Presentation on overall concept and key features of establishment risk control, and questions for group input (*45 minutes*)
 - Facilitated group discussion (*15 minutes*)
- 1:15 – 2:30** **Lunch**
- 2:30 – 3:30** **Group Discussion: Product Inherent Risk & Establishment Risk Control**
Facilitator, RESOLVE
- Facilitated group discussion about product inherent risk and establishment risk control
- 3:30 – 3:45** **Overview of and Instructions for Small Group Discussions**
Facilitator, RESOLVE
- Explain format, process, and intended outcomes of small group discussions; and
 - Transition to small groups

- 3:45 – 5:30** **Small Group Discussions: Key Components of RBI**
Facilitators, RESOLVE
- Discuss strengths and weaknesses of key component concepts and ideas;
 - Discuss and develop suggestions and options for improving key components; and
 - Prepare brief group report (*final 15 minutes*)
- 5:30** **Adjourn for the Day**

Wednesday, October 11

- 9:30 – 9:45 am** **Reflections on Day 1 and Review of Day 2 Agenda**
Facilitator, RESOLVE
- Summation of Day 1 presentations and discussions
 - Review Day 2 agenda
- 9:45 – 11:15** **Small Group Reports and Full Group Discussion**
Small Group Representatives; Facilitator, RESOLVE
- Present small group reports from Day 1; and
 - Facilitated group discussion about results of small group discussions
- 11:15 – 11:30** **Break**
- 11:30 – 12:15 pm** **Preliminary Ideas on Using Risk to Direct In-Plant Inspection Activities in Processing Assignments**
Bobby Palesano, Deputy Executive Associate, OPPED, FSIS
- Presentation on overall concept and key features of using risk to direct in-plant inspection activities in processing assignments and how it fits together with other components; and
 - Questions for stakeholder input
- 12:15 – 1:30** **Lunch**
- 1:30 – 2:30** **Group Discussion: Using Risk to Direct In-Plant Inspection Activities in Processing Assignments**
Facilitator, RESOLVE
- Facilitated group discussion about ideas on using risk to direct in-plant inspection activities in processing assignments of RBI
- 2:30 – 3:30** **More Group Discussion on Topics of Interest**
Facilitator, RESOLVE
- Identify and engage in facilitated discussion about areas and/or issues that could benefit from further consideration during this meeting

- 3:30 – 3:45** **Break**
- 3:45 – 4:20** **Assessment of Workshop Discussions and Ideas for Moving Forward**
Dr. Barbara Masters, Administrator, FSIS
Dr. Richard Raymond, Under Secretary of Food Safety, USDA
- Recap highlights and key issues raised during the workshop, and discuss ideas about how to move forward following the workshop
- 4:20 – 4:30** **Summary and Wrap Up**
Facilitator, RESOLVE
- Summary and wrap up of workshop proceedings.
- 4:30** **Adjourn**

C.4: Risk-Based Inspection Public Workshop Attendance

Location	FSIS Employees	Industry, Consumer groups, etc.	Total Attendees
On-site in Arlington	46	99	145
Alameda, CA	3	0	3
Albany, NY	4	0	4
Athens, GA	2	1	3
Atlanta, GA	3	1	4
Beltsville, MD	3	0	3
Chicago, IL	10	1	11
Dallas, TX	4	3	7
Denver, CO	14	4	18
Des Moines, IA	3	0	3
Fredericksburg, PA	0	1	1
Jackson, MS	4	18	22
Lawrence, KS	8	0	8
Madison, WI	9	0	9
Minneapolis, MN	2	1	3
Palmyra, PA	0	7	7
Philadelphia, PA	17	2	19
Raleigh, NC	4	2	6
Reynoldsburg, OH	4	6	10
Springdale, AR	5	18	23
Omaha, NE	10	3	13
College Station, TX	6	0	6
Starkeville, MI	0	3	3
Pittsburgh, PA	3	8	11
Washington, DC	2	0	2
Totals	166	178	344

C.5: List of RBI Electronic Submittals

- Ramon Amoureux, Unknown
- Susan Backus, National Meat Canners Association
- Minuand D. Bailey, Clovervale Foods
- Trent Berhow, Unknown
- Richard Bishop, FSIS
- Andrea Brown, American Association of Meat Producers
- Mark D. Dopp, American Meat institute and Craig Henry, Food Products Association
- Sulatha Dwarakanath, Nano Science Diagnostics, Inc.
- Sandra Eskin, Safe Tables Our Priority
- Ron Fouche, Palmyra Bologna
- James L. Grems, FSIS Minneapolis, MN District Office
- Lydia M. Guillot, FSIS/USDA Field Operations, Charlotte Circuit, Raleigh District
- Wenonah Hauter, Food & Water Watch
- John Hopperstad, Unknown
- Ken Kelly, Center for Science in the Public Interest (CSPI)
- Ellie Krise, Cattle Ranch Owner
- Christy Marr, National Turkey Federation
- Noam Mohr, People for the Ethical Treatment of Animals (PETA)
- Glenn Mott, Gerber's Poultry, Inc.
- John W. Munsell, Montana Quality Foods & Processing and Foundation for Accountability in Regulatory Enforcement (FARE)
- Jacqueline Ostfeld, Government Accountability Project
- Anne Powell, Leon's Texas Cuisine
- Jim Rasekh, FSIS
- Paul Resweber, FSIS Jackson, MS District Office
- Samuel Robins, Unknown
- David Thompson, FSIS Jackson, MS District Office
- Joe Tiscia, Unknown
- Mike Vaupel, Unknown
- Christopher Waldrop, Consumer Federation of America
- James Brian Waugh, FSIS, Perdue Farms
- Unknown A
- Unknown B