

October 27, 2006

Ellyn Blumberg  
RBI Public Meeting  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
14<sup>th</sup> St. and Independence Ave, SW  
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Washington, DC 20250

**Re: Risk-based Inspection System, Docket No. 2006-0028; 71 *Fed. Reg.* 56470 (September 27, 2006).**

Dear Sir/Madam:

The American Meat Institute (AMI or the Institute) and the Food Products Association (FPA) submit the following comments regarding the above-referenced notice published by the Food Safety and Inspection Service (FSIS or the Agency).

AMI represents the interests of packers and processors of beef, pork, lamb, veal, and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb, and veal products, and 70 percent of the turkey products in the United States. The Institute provides legislative, regulatory, public relations, technical, scientific, and educational services to the meat and poultry packing and processing industry.

All of AMI's general members are subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, or both. Although AMI represents many of the largest meat packing and processing companies in the country, more than 75 percent of AMI members are small businesses. For these reasons, AMI has a direct interest in the implementation of a risk-based inspection (RBI) system.

The Food Products Association is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists, and professional staff provide technical and regulatory assistance to member companies and represent the food industry

on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs, and international trade.

In addition to the comments that respond to questions posed by the Agency at its recent public meeting, AMI and FPA are undertaking a more comprehensive and in-depth examination of the elements required for successful risk-based inspection implementation. Recommendations derived from that effort will be shared with the Industry RBI Coalition and any recommendations developed there will be submitted to the Agency before the end of this year. We look forward to working closely with the Agency and all interested stakeholders to help bring this important initiative to fruition.

FSIS presented a number of questions at its October 10-11, 2006 public meeting. The comments that follow address those questions, as well as additional points for the Agency's consideration.

### **GENERAL COMMENTS**

AMI and FPA strongly support the concept of risk-based inspection and applaud FSIS for being as transparent as possible in developing this concept. Soliciting input from all stakeholders, although controversial at times, will lead to a RBI program that is more robust and more acceptable to everyone.

RBI is a simple concept with an easy-to-understand end result, *i.e.*, allocation of limited Agency resources where they are most needed on the basis of food safety risk so as to minimize the occurrence of foodborne illness and maximize the protection of human health. Any discussion of RBI, however, starts with the proposition that products produced under FSIS inspection and bearing the mark of inspection should be regarded as wholesome and not adulterated. This important point should be emphasized by FSIS to ensure that all businesses meeting regulatory requirements are in a position to market and sell their products without a misconception that somehow their products are unsafe or unwholesome.

Under RBI, establishments processing products with the highest likelihood of causing human illness, in particular establishments with lesser risk control, will receive more intense application of inspection resources. If the Agency has reason to believe that the products of any establishment are unsafe or fail to meet critical regulatory requirements, the Agency has an obligation to withhold the mark of inspection or withdraw inspection service from that facility.

Although FSIS is focused on the risk-based application of resources in meat and poultry processing establishments and has just begun to consider applying RBI to slaughter operations, the Agency should also consider longer term plans to apply RBI over the broader food supply chain continuum from farm to table. With the goal of reducing foodborne illnesses caused by meat and poultry products, a risk-based allocation of resources may pay greater dividends when the focus is upstream from the establishment or more likely, further downstream at institutions, retail establishments, and restaurants. For example, recent survey work supported by USDA shows that contamination of ready-to-eat (RTE) meat and poultry products with *L. monocytogenes* occurs at retail, leading to a higher incidence of contamination on products sliced at retail than on pre-packaged products produced at federally-inspected establishments.<sup>1</sup> Only by examining the entire food supply chain will resources ultimately be directed where they are most needed to optimize risk reduction and enhance public health.

FSIS should predetermine the measures it will use to gauge successful implementation of RBI. In that regard, many relevant measures exist today, *e.g.*, verification testing data, and changes in the number of foodborne illnesses attributable to meat and poultry products; however, additional measures, such as a reduction in resources spent on non-food safety-related noncompliance records (NRs), both by FSIS inspection staff and establishments during the initial issuance and the appeal process, and improvements in operations (*e.g.*, lowered risk ranking) at establishments where inspection resources are increased will also be important indicators of success.

FSIS should emphasize that, along with RBI and the allocation of resources based on PIR and ERC, there will be a renewed effort to focus inspection staff on efforts to educate inspected establishments (especially small and very small establishments) on methods to improve food safety. Such an effort will enhance the position of FSIS not only as a regulatory agency but also as a government entity that works cooperatively with all stakeholders to enhance food safety and protect public health.

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<sup>1</sup> Daughon, F.A. 2006. A collaborative risk assessment of *Listeria monocytogenes* in ready-to-eat processed meat and poultry products based on 8,000 samples collected from four FoodNet sites., Presented at the 93<sup>rd</sup> Annual Meeting of the International Association for Food Protection, Calgary, Alberta, Canada, August 13-16, 2006.

## **FSIS Should Use Objective Measurements**

A challenge facing FSIS in implementing RBI is separating subjective assessments from objective measures, and using quantitative measures in lieu of qualitative measures. These evaluations are discussed within the answers to the questions addressed in this document; however, the Agency's ability to address these differences is critical to developing and implementing a successful RBI system.

Using an algorithm to categorize establishments in order to allocate resources requires the consideration of as many relevant facts as possible. By using indisputable objective measures FSIS will minimize time spent defending its categorization of establishments, as well as clarify for establishments the requirements for minimizing risks in a measurable manner. The more subjective the measurements, the more divisive and controversial the RBI process will become. Recognizing that all stakeholders may not agree on the categorization of establishments regardless of how determinations are made, it is important that FSIS has a well-defined process for conflict resolution.

## **FSIS Should Include Positive Data**

FSIS should use "positive data" as well as "negative data" when assessing establishments. Too often the focus is on the negative aspects of inspection, looking for deficiencies as a gauge of risk control. FSIS should use positive performance factors to reflect not only industry performance, but also the Agency's job in overseeing meat and poultry production in a positive manner. If FSIS considers the production that occurs day after day in a successful manner, it could speak to the high measure of success of the meat and poultry production process and reflect on the successful cooperation between FSIS and industry in risk control. In making the determination as to where an establishment falls within a Product Inherent Risk (PIR) and Establishment Risk Control (ERC) grid or in a risk ranking continuum, FSIS may find that a given establishment is more accurately categorized by examining positive compliance data (e.g., PBIS tasks performed successfully) associated with that facility, in addition to other information indicative of non-compliance (e.g., food safety-related NRs).

## **FSIS Should Consider the Implications for International Trade**

FSIS also needs to ensure that RBI is compatible with international expectations such that implementation of RBI does not adversely affect international trade or the concept of equivalency with our international trading partners. In that regard, FSIS should recognize that foreign

inspection agencies may adopt equivalent RBI approaches. If so, products manufactured under such a system must be allowed into this country without unwarranted, costly, and disruptive inspection, sampling, and testing for microbiological and chemical hazards at the border or ports of entry. Although FSIS has a responsibility to ensure that imported products do not pose food defense risks, such sampling and testing procedures should remain separate from food safety-related sampling and testing that can be managed through an equivalent food safety systems in the foreign country before shipment. To facilitate international trade FSIS must keep its trading partners informed about the development of an RBI inspection system.

### **FSIS Should Consider a Continuum as an Alternative to a Matrix**

As an alternative to the quadrant matrix illustrating the relationship between the PIR and ERC, FSIS might consider a continuum of plant ratings that incorporates all components of the two dimensional matrix, including PIR, ERC, production volume, and interventions. Although there are advantages to the matrix approach, FSIS may determine that placing establishments along the continuum offers more advantages than trying to separate establishments into different levels or categories where the distinction between one category and another may be difficult to justify and lead to disagreement and wasted resources attempting to defend the positioning of establishments in one level as compared to another.

AMI and FPA are in the process of outlining an algorithm that incorporates the factors mentioned above and describes appropriate weightings to provide a single establishment ranking. Such an algorithm could address the issue of ranking plants that produce multiple products that would fall into different boxes within a matrix. Moreover, this algorithm could be modified to establish a matrix similar to what FSIS proposes, if such an approach is desirable. It will be beneficial, if not essential, to test any potential algorithm with multiple hypothetical plant parameters to assure that it yields logical results.

### **The PIR Expert Elicitation Should be Revisited and Expanded**

As FSIS heard at the public meeting there are questions and concerns related to the expert elicitation that resulted in the “risk ranking” of the product categories. Most questions related to the lack of an upper boundary for the experts’ scoring, the confusion surrounding the lack of consideration of “severity” in the ranking (although the thought process used by experts likely would consider this, even if unintentional), and the composition of the expert panel.

At the public meeting, it was strongly suggested that additional input on the PIR elicitation was needed. The expert elicitation should be used as the basis for additional input from industry, public health officials, and knowledgeable academic experts in food safety to further define PIR. To facilitate a full exchange of ideas needed to develop a consensus on and a rational basis for the risk rankings, this additional expert elicitation should be conducted face-to-face rather than by correspondence. These experts should also be asked whether the initial list of product types is complete or should be modified or expanded.

## **ANSWERS TO QUESTIONS ASKED AT THE PUBLIC MEETING**

During the October 2006 public meeting several FSIS officials provided presentations regarding the development of RBI. Included in those presentations were a number of questions posed by the Agency as it seeks information and perspective from interested entities. Provided below are our responses to the questions presented.

### **Questions and Answers Regarding Product Inherent Risks**

**Question 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?**

In considering the expert data, an alternative to using the raw median scores would be to normalize individual data sets for each expert on a scale of 1 to 100 before using the median score. Using this approach the Agency would take into consideration the scores of all experts for all products. In the event the Agency convenes a group to reconsider PIR, it can also solicit further input on this matter.

**Question 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?**

Commercially-sterile products should be included in the lowest-risk category. The controls over canning are stringent; and the lethality is very conservative. Failures are very rare as supported by historical data; and the low incidence of botulinum spores means that failures rarely result in toxigenesis preceding overt spoilage. Again, in the event the Agency convenes a group to reconsider PIR, it can also solicit further input on this matter.

**Question 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?**

When determining the inherent risk of a product that is to be further processed,, the Agency should consider if the product will be further processed at another establishment within the same corporation, at another federally-inspected establishment, or elsewhere. The Agency should consider also the final use of the product (*e.g.* fully cooked shelf-stable, partially cooked non shelf-stable, raw) and the intended consumer when determining the inherent risk of the product. For example, product produced solely for incorporation into a fully cooked, shelf stable product (*e.g.*, raw ground beef for chili) should not require the same level of regulatory scrutiny as the same product produced for direct sale to consumers (*e.g.*, pre-packaged raw ground beef).

FSIS has recognized that companies can move products between official establishments for further processing with appropriate controls to assure that product will reach the appropriate destination for further processing. Transport of product from one federally-inspected establishment to another within the same corporate structure is even more secure. When establishments are able to demonstrate that product is produced solely for the purpose of further processing and has records to demonstrate that the product reaches the intended destination, the Agency should take that information into consideration when determining PIR.

Finally, further processing that may occur at retail should not be factored into the risk determination because regulatory oversight at retail is limited.

**Question 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?**

There was much discussion at the public meeting surrounding whether “volume of production” was an appropriate indicator of PIR. Although volume of product could affect the impact of contaminated product on public health, it does not affect the inherent risk of a meat or poultry product. The suggestion that the Agency use production volume as a third axis of consideration, along with PIR and ERC highlights the issues attendant to the use of production volume in determining exposure. Furthermore, 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.

Exposure could 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. The conversion of production volume into servings, and thus to any of these metrics, is straightforward. However, whichever metric is used, there are important factors that need to be considered in relation to production volume.

In that regard, the processed product may be further processed into other lower risk products at federally-inspected establishments, *e.g.*, raw ground beef into partially- or fully-cooked beef patties, or raw poultry breasts into fully-cooked, breaded, frozen breasts. Calculating exposure for the raw ground beef or raw poultry breasts based on production volumes without considering such further processing would be misleading and an over-estimation of the exposure. Thus, when calculating exposure based on production volume, unless the products are going directly to consumers in retail-ready packages, the conversion of volume to exposure is not direct and intermediary process steps must be considered.

**Question 5 – Measurement of Inherent Risk in Processed Meat and Poultry Products: Given that most establishments produce more than one type of product, how should inherent risk data for each establishment be presented?**

The simplistic answer to this question is that the Agency should assign a value based on the “most risky” product issuing from that establishment. However, the Agency, or the Agency’s algorithm, should not blindly apply a value simply because an establishment makes a particular product. Keeping in mind that RBI is a system intended to allow the Agency to apply resources to maximize the effectiveness of inspection, and hence food safety, FSIS arguably must consider not only the various products made, but how much of the “riskier” product the establishment produces and the frequency of that production.

For example, two plants may make a product that falls within one of the product categories identified by FSIS as inherently more risky. However, Plant X may produce only one tenth, or less, of the amount of that produced at Plant Y.<sup>2</sup> Therefore, not only should the amount of product coming from the plant be part of the calculus, but the frequency of production also may be a relevant factor in determining resource allocation. For example, perhaps Plant X only produces the product on one shift on one day each week. That circumstance may be quite different from an establishment where the product is made daily. Added to these

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<sup>2</sup> As comments above have indicated, volume in and of itself, does not affect the inherent risk of the product.

considerations is the fact that the remaining products processed by a plant may fall into the extreme other end of the PIR spectrum. In short, concluding that a plant automatically starts at a particular point on an axis simply because it produces a particular category of product is overly simplistic. In constructing any sort of algorithm to determine risk and resource allocation, this component of the model must consider an array of factors when deriving a value.

Another useful approach would be to have the establishment or FSIS plot all of the individual products produced at an establishment on the two- or three-dimensional matrix (PIR versus ERC, with volume for the additional axis in a three-dimensional matrix). Thus, the inspection staff and the establishment would be able to visualize the risk array for the entire profile of products. This concept would need to be further developed to determine the appropriate weighting to be given to various products plotted on the two or three dimensional establishment matrix.

Another approach would be to apply the algorithm that AMI and FPA are developing to each product the establishment produces to obtain a risk ranking. The plant ranking would be adjusted based on a weighted volume (greater weight given to higher risk rankings), with the values generated for all products produced averaged to obtain a final plant value. FSIS could be notified when a plant with generally low risk ranking is producing a high risk product to allow for inspector presence, as appropriate.

**Question 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?**

The severity of illness will be affected by the type (species and strain) and quantity (infectious dose) of the hazard present in the food at the time of consumption and the susceptibility of the consumer (*e.g.*, age, health, immune system) exposed to the hazard. A worst-case scenario is not the appropriate measure for all meat and poultry products; however, if a specific product is targeted for consumption by a more-vulnerable segment of consumers (*e.g.*, children or the elderly), then a “severity of illness” factor should be considered in the assessment and factored into the PIR. Historical foodborne illness data, although not comprehensive, can assist in evaluating the link between specific meat and poultry products and foodborne illnesses, and the severity of these illnesses. The public meeting made clear that FSIS, FDA, and CDC need to continue to work cooperatively to improve the acquisition and use of food attribution data.

Any effort to develop a risk-ranking of meat and poultry products requires a sound rationale for that ranking. This rationale likely includes consideration of the type of hazard most likely to be associated with the product based on published (*e.g.*, FSIS verification, academic) or unpublished (*e.g.*, industry) data. Identification of the hazard of concern allows severity to be more predictable based on consideration of various factors, such as targeted customers and consumers, product packaging, further processing by federally-inspected establishments, institutions, retail and restaurants, and consumer handling and preparation. Also, historical foodborne illness data and available food attribution data can assist in making a determination on the severity of any illness. At the conclusion of the severity assessment, the ranking of the meat and poultry products may be adjusted to reflect the impact of the “severity factor.” Indeed, a new expert elicitation could include severity as a component of the PIR.

### **Questions and Answers Regarding Establishment Risk Control**

#### **Question 1 – Measuring Establishment Risk Control for RBI: Are these 6 components appropriate and adequate?**

Presentations at the public meeting by the Agency identified six components of an analysis to measure ERC. They include food safety system design, food safety system implementation, pathogen control, in-commerce information, food defense, and enforcement actions. The first four components have an appropriate role to play in measuring ERC. However, the last two, food defense and enforcement as explained by the Agency at the public meeting and the related background documents published by FSIS, should not be part of that analysis as individual components for reasons described herein.

Evaluation of an establishment’s food safety system design and the implementation of that system are the cornerstones of any analysis of a plant’s risk controls. In that regard, system design and system implementation are elements over which the plant has the most direct control. Significantly, the pathogen control and in-commerce elements put forward by the Agency as considerations of ERC provide certain measurable results but are really outcomes of the effectiveness of the design and implementation. All four components are legitimate factors for FSIS to use in estimating ERC, but the first two are the core of the control system while the latter two provide measures emanating from the former. With that in mind, it would be appropriate for the Agency in developing the algorithm or other analytical tool to give greater weight to system design and system implementation in comparison to pathogen control and in-commerce results.

In contrast, the Agency should not include in the analysis the proposed elements of food defense and enforcement actions. We recognize the importance of food defense and we encourage all establishments to prepare and implement a substantive food defense plan. Furthermore, many elements in a plant's system design should complement a food defense plan to the extent there is a cross-over between ensuring food safety and mitigating risks at critical nodes in a food defense plan. Food defense, however, should remain a separate initiative from RBI.

Enforcement actions also are not measures of ERC but are actions taken by FSIS or some other entity that may not always be directly related to food safety, at least not in the context provided by FSIS in the public meeting or the Agency's papers. In that regard, to the extent elements of the enforcement action component relate directly to food safety and establishment control, they likely belong more appropriately as part of system implementation or the in-commerce component. Indeed, the three elements cited by FSIS that would make up the enforcement actions component are either ambiguous as to their nature or arise from elements captured elsewhere, or both. For example, the Agency cites "NOIEs not captured elsewhere" as an enforcement action that would be part of the algorithm. It is difficult to imagine, however, a Notice of Intended Enforcement (NOIE) that does not emanate from a food safety assessment (FSA), system design, or some in-commerce or pathogen control related circumstance. Similarly, injunctive actions and consent decrees inevitably have their foundation or "root cause" in one of the other components that should be included in the analysis. To incorporate such actions into the calculus of ERC as an additional, stand-alone element would, in essence, be double counting the impact of that event. Accordingly, the Agency should eliminate food defense and enforcement actions from the ERC analysis.

A factor that may be important in the consideration of pathogen control data is whether the types of products processed at an establishment have led to the collection of verification data by FSIS or by the establishment. Absence of data by FSIS or the establishment may or may not suggest a particular risk is associated with production of those products; however, these situations should be examined and not discounted.

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

Objective components should be used rather than subjective components when determining ERC. Data provided in the Agency's diagram as "system design," "system implementation," and "pathogen control" are objective and should factor into the Agency's ERC determination. However

other information, such as consumer complaints and many NRs, can be highly subjective. Before incorporating such information into an analysis, the Agency must have the ability to quantify that information so it is used in a manner consistent with the science-based, quantitative information generated elsewhere.

There is considerable controversy about how to quantify and incorporate NRs into the assessment. The Agency should host a working group to look at sample, blinded NRs to attain consensus regarding those NRs that relate directly to food safety. Such an approach would help the Agency develop a drop-down menu for electronic NRs, simplify the NR writing process for inspectors, and greatly improve the Agency's ability to search its NR database. This working group could also assign appropriate weighting to the various types of NRs based on their impact on food safety, which should greatly facilitate the Agency's ability to quantify the significance of NRs.

As stated above, whether the establishment has a voluntary food defense plan should not affect the Agency's determination of ERC. Food defense is a separate initiative from that of food safety and is outside the scope of this project and the intent of RBI.

### **Question 3 – Is there other useful information about establishments' risk control that FSIS is not considering?**

The most important information not considered by the Agency pertains to the interventions that an establishment has in place to reduce risks. As indicated previously, most interventions could be incorporated into PIR by increasing the number of categories of product types. If the Agency chooses not to take that approach, then interventions certainly must be addressed in ERC. Although one might consider system design to include interventions, the use of validated interventions is one of the most important actions that an establishment can take to control risks. For this reason, the use of interventions as a criterion outside of system design or implementation may be advantageous in assessing risk control.

A second area that the Agency has not considered is the role that company testing programs and data can play in assessing ERC, *e.g.*, establishment testing programs for controlling pathogens. We will demonstrate in the algorithm being developed how company testing programs can be incorporated.

Other information would include the use of “select supplier programs” that lead to the use of proven suppliers of raw materials to the manufacturing process. Such programs would need to meet certain criteria, such as signed specification agreements, crisis management programs, stock recovery plans, historical production records, testing data, and auditing trails that verify that these specifications are being met.

Any algorithm that is developed should be transparent so that an establishment can perform its own calculation. Any establishment should be permitted to discuss with the Agency concerns that some factor has been misapplied or omitted by the Agency in its calculation. Omitted data could include establishment data the company is willing to share with the Agency.

Again, FSIS should consider the production matrix at the establishment, *i.e.*, the number of different products that are produced, the schedule for producing the different products, the relative volumes of the products, and the flow of raw materials and finished goods throughout the facility. The sequencing of production of these multiple products may have an impact on risk unless the establishment recognizes the challenges and adjusts their management controls appropriately.

#### **Question 4 – Are there other ways besides Food Safety Assessments to evaluate establishment food safety system design?**

In addition to FSAs, the Agency should consider the establishment’s history of producing safe food when determining ERC. Although compliance with regulatory requirements is important, the goal of those requirements is to ensure that the establishment is producing safe food. History can be a significant indicator of the successful implementation of an establishment’s food safety system.

The Agency should consider the number of food safety-related NRs and the substance of those NRs received by an establishment between FSAs. An establishment that has received very few NRs likely requires less regulatory scrutiny than an establishment that has received NRs for critical food safety violations at a rate well above the norm. However, the element of consistency of inspection and issuance of NRs must be carefully reviewed before making broad and specific interpretations of the quantity and type of NRs associated with individual establishments.

Today, the most common outcome of a less than perfect FSA is either one or more NRs or a NOIE. The Agency must consider carefully the findings of the FSA when determining an ERC, rather than simply checking a box that indicates an NOIE was issued as a result of an FSA.

An Enforcement, Investigations and Analysis Officer (EIAO) may find inconsistencies in the way a HACCP plan is written and implemented as part of the FSA. However, the written inconsistencies frequently are not critical to the production of safe food. For example, the FSA may report that a flow chart included in a HACCP plan does not match the actual product flow in the plant. Although this inconsistency may be a noncompliance, so long as the hazard analysis has taken all likely hazards into consideration and those hazards are being eliminated or minimized through the process, the error in the flowchart is inconsequential to the production of safe product. Many similar examples could be cited.

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

The presentations provided at the public meeting did not make clear which NR categories FSIS is considering. One slide at the meeting suggested that the Agency was considering NRs issued for 9 CFR § 416.15, SSOP corrective actions, and § 417.3, HACCP corrective actions. Noncompliant performance within these categories may or may not be indicative of a public health-related noncompliance. They are, however, the types of NRs the Agency should examine for their impact on food safety. The Agency might also consider NRs involving 9 CFR 417.6(e), Inadequate HACCP System, adulterated product shipped, because these NRs can indicate a loss of control by the establishment. As discussed previously, FSIS should work closely with the affected industry to define which NRs directly impact food safety and are thus relevant to ERC determinations.

The Agency heard on numerous occasions during the public meeting that NRs under appeal should not be incorporated into the Agency's evaluation of the ERC until the appeal has been reviewed and resolved. That is the appropriate approach and doing so likely will encourage the Agency to review appeals expeditiously so that, if sustained, they may be factored into the assessment of an ERC.

**Question 6 – What is an appropriate lookback window?**

With the understanding that the lookback window will be based on data generated over the course of a moving or rolling time frame, a lookback window of not less than six months and not more than one year should provide an opportunity for an accurate assessment of an establishment. An establishment also should be permitted to request a reconsideration or reassessment of the ERC if the plant can demonstrate a significant or noteworthy change has been made that could affect the assessment. For example, a plant might incorporate new technologies that move the

classification of the products it processes from Alternative 3 to Alternative 1. Such a change might have a dramatic impact on the value or assessment incorporated into an algorithm with respect to system design.

### **Questions and Answers Relating to Implementation**

As FSIS defines its multiphase roll-out of RBI, it may be advisable to begin the process at establishments with the lowest PIR and best ERC because they offer a safe harbor for roll-out of RBI. Once proven successful, the RBI process could be expanded to other establishments. At the public meeting a suggestion was made to pilot the program, which seems reasonable. Piloting the program in a single District or, alternatively, piloting in various circuits within several different Districts may give an overall indication of where adjustments need to be made before the program is implemented nationwide.

#### **Question: How many levels of inspection are optimal?**

More significant than the number of levels of inspection is that the Agency ensures that, in determining a particular establishment's level, it uses quantitative data. Some of the data identified and discussed at the public meeting as relevant to the assessment and applicability of RBI are quantitative. Conversely, much of the information the Agency has identified is qualitative. Although the discussion papers provided by the Agency and the issues they present need further thought and consideration, it is imperative that, if the Agency is going to approach RBI through the use of algorithms or some other modeling technique, it should not allow non-quantitative, subjective information to overrule the values delivered by the model. Such an approach makes it paramount that the Agency does what is necessary to ensure that the model or algorithm is the best possible. In short, the Agency must not create a system that allows subjective decisions based on qualitative information to overrule scientific, fact-based data.

As mentioned earlier in this report, FSIS may wish to use a continuum of risk rankings. This linear approach need not have categories or even published numeric scoring, yet it can serve as the basis for RBI with less controversy and necessary justification by FSIS.

#### **Question: How do plants move from one level to another?**

Embodied in the answer to this question is the Agency's review of data and other quantitative information as discussed above and through the vehicle of a lookback window (See Question 6 in the Establishment Risk Control discussion). The Agency's representations at the public meeting 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. Both options should be permitted, however.

**Question: How frequently should FSIS evaluate data to make decisions on the plant moving from one level to another?**

As discussed in Question 6 above, a six month to one year rolling lookback window should provide an opportunity for an accurate assessment of an establishment. The normal frequency for recalculating an establishment's risk ranking should be monthly. The District Office would allocate resources based on this ranking. If an establishment makes changes that would significantly change its ranking (*e.g.*, by adding a new intervention), then the firm should be able to request a recalculation based on the new information. Likewise, if the Agency takes enforcement action against a firm, it may be appropriate to recalculate the risk ranking before the next regularly scheduled monthly reassessment and reallocate resources for the current period.

**Question: Should we use predictive indicators?**

The October 2006 public meeting indicated that more definition and information regarding the concept of "predictive indicators" is needed to clarify what these are and how they would be used by inspection personnel with respect to RBI. It appears from the examples given in the FSIS presentation that predictive indicators are situations or events that would indicate that a higher level of inspection may be warranted. However, key to the Agency's reaction to such predictive indicators should be how the establishment manages these situations or events. If the establishment has implemented 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. Much of this could be managed in the weekly meeting or by proactive notification of the inspection staff by the establishment. This is an area where subjective interpretation of situations could lead to disagreements about the significance of a predictive indicator and provides a compelling reason for the Agency to be able to quantify a factor before considering it in the context of RBI.

**Question: How would we capture predictive indicators?**

As mentioned above, weekly meetings and proactive communication from the establishment to the inspection staff regarding special circumstances or events that could result in a predictive indicator situation are two means of capturing the information. In all cases, having a pre-determined list of examples of predictive indicators with objective measurement criteria would help facilitate this communication and sharing 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.

**Question: What are other examples of predictive indicators?**

In addition to the examples provided by FSIS in the public meeting, the following may possibly be 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.

**Recommended Food Safety Inspection Activities for Different Inspection Levels**

In the wake of the public meeting it is apparent that FSIS would like recommendations for the types of inspection activities that minimally should be conducted at establishments that fall into the various risk categories. It may be premature to define these types of activities until there is a better developed structure for ranking establishment risk. Nevertheless, in general, the focus should be on more intensive inspection activity for plants that are having trouble controlling the risks.

AMI and FPA appreciate the opportunity to submit these comments and would be pleased to meet with Agency officials to discuss further the issues presented and these comments. We also understand that the Resolve Report will be issued in December 2006 and look forward to the opportunity to review and comment on this report.

Sincerely,



Mark D. Dopp

Senior Vice President,  
Regulatory Affairs  
and General Counsel  
American Meat Institute



Craig Henry

Senior Vice President,  
Scientific and Regulatory Affairs  
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Food Products Association