

Food Safety and Inspection Service/USDA
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**Comments Submitted by the American Meat Institute for the National Advisory
Committee on Meat and Poultry Inspection Fall Meeting, November 15-16, 2005**

AMI, November 14, 2005

There has been a succession of publications by the Food Safety and Inspection Service (FSIS, or the agency) regarding risk-based inspection (RBI). For example, in 1999 (*Improving the Safety of Meat and Poultry: Background on a Science-based Strategy for Protecting Public Health*), FSIS anticipated "... a major redeployment of its inspection resources to successfully implement HACCP and better target food safety hazards during transportation, storage, and retail sale." In 2004 (*Fulfilling the Vision: Initiatives in Protecting Public Health*), FSIS stated that "... it is essential that the agency continue to modernize its inspection system through risk-based approaches and further refine its management agenda in order to have the flexibility to meet ever changing threats to public health." Progress regarding development of RBI, however, has been slow. The American Meat Institute is pleased that public discussion over RBI is being initiated through the work of the NACMPI.

In its Vision document, FSIS notes the potential use of a criterion such as a Hazard Control Coefficient (HCC) as a measure to describe "how well each [plant] is complying with agency regulations" and to serve as an indicator of plants in need of attention, "... thereby ensuring better use of agency resources." Non-compliance records (NRs) and other data, such as verification sampling results, have been suggested by FSIS as criteria for calculating the HCC. Current NR data as a prominent evaluative factor would limit the value of any such predictive tool for establishment risk, primarily because a substantial portion of today's NRs are not directly linked to food safety (data, already shared with FSIS, is available from industry upon request). If NRs are to be used as a component of establishing a risk profile, then limiting NRs to, or at least weighting them toward, issues of food safety significance would provide FSIS with much more useful information about how well a firm is fulfilling its food safety obligations. Whatever the criteria used to assess risk for RBI, they should be linked by scientific data to their public health consequences.

RBI, when based on criteria that adequately and accurately reflect public health risks, is a logical step in allocating resources to further improve food safety and decrease public health risks. Keys to successful RBI are getting the right criteria for assessing the risk, sharing relevant data amongst the stakeholders, and having clear links between foodborne illness and specific products. Cooperation and transparency will be paramount in the joint effort to successfully develop and implement a system for risk-based allocation of inspection resources. Industry stands ready to do its part in the cooperative effort.

The development work on an effective, meaningful basis for RBI can best be accomplished through a transparent process involving everyone with constructive ideas for optimizing the system, *e.g.*, a public meeting and task force. RBI is an ideal candidate for a new cross-

functional, transparent approach by FSIS. Important issues related to executing RBI include the confidentiality of establishment-specific risk-rankings, measuring the effectiveness of RBI by FSIS, industry and other stakeholders, and managing misunderstandings and disagreements related to RBI to continuously improve the process.

Factors such as (1) the compliance history of the establishment, (2) the nature of the product, (3) the nature and reliability of the plant's food safety controls, (4) the production volume when considered in conjunction with the other factors, (5) seasonal and regional factors, (6) the complexity of the operations, and (7) the competence of the operations' staff should be considered to optimize risk analysis and resulting RBI. The use of such factors would be supported if there were some data linking the factor (specifically, the various measurements that can be used to assess and track the factor) to public health outcomes. To date, such linkages have not been revealed or completed, and have not been supported by data.

Criteria that may be associated with the factors include:

Compliance history of the establishment

- NRs when appropriately weighted toward compliance with food safety related regulatory requirements
- The likelihood and significance of potential public health consequences that could result from noncompliance
- Food safety assessment results, if linked to public health
- FSIS microbiological verification testing results, if linked to public health
- FSIS enforcement actions, if linked to public health
- Product recalls, if linked to public health.

Nature of the product

- Public health risk associated with product including foodborne illness outbreak attribution data and microbial risk assessments
- Presence of microbiological hazards and quantitative levels to the extent known, if linked to public health
- Presence of physical or chemical hazards, if linked to public health
- Potential for product mishandling, if linked to public health
- Target consumer
- HACCP category
- Shelf life of refrigerated foods, if linked to public health.

Nature and reliability of food safety controls

- Procedures used to control the production process, environment, and resulting product, if linked to public health
- Use of microbiological interventions that kill microorganism (in particular, a kill step delivered to packaged product)
- Use of microbiological interventions that prevent or limit microbial growth

- Verification and validation of interventions, if linked to public health
- Use of appropriate prerequisite programs for potential hazards not addressed in a HACCP plan, e.g., allergen control programs and environmental monitoring programs
- Use of microbiological verification testing and the results obtained, if linked to public health.

Production volume

- Amount of product manufactured, irrespective of HACCP plant size designation (*i.e.*, very small, small or large), if linked to public health
- Significant in regard to number of consumers potentially at risk from unsafe product, but must be considered in conjunction with the likelihood of unsafe product being produced and shipped.

Other Considerations

- Seasonal or regional factors that can impact the public health risk of the product
- Complexity of the processing operation(s) conducted at the establishment, if linked to public health
- Competence of persons conducting operations as indicated by: knowledge of manufacturing practices and regulatory requirements, demonstrated ability to apply such knowledge in a timely and consistent manner & commitment to correcting deficiencies and assuring compliance with regulatory requirements.

The American Meat Institute joins the broader industry coalition, including the American Association of Meat Processors, the Eastern Meat Packers Association, the Food Products Association, the National Meat Association, the North American Meat Processors Association, the National Chicken Council, the National Turkey Federation, the Southwest Meat Association, the U.S. Poultry and Egg Association, and their members, in its support of the common goals with FSIS to improve food safety and reduce the risks to public health. We believe that RBI, when based on criteria that adequately and accurately reflect risks, is a logical step in allocating resources to further improve food safety and decrease public health risks. Keys to successful RBI are getting the right criteria for assessing the risk, sharing relevant data amongst the stakeholders, and having clear links between foodborne illness and specific products. Cooperation and transparency will be paramount in the joint effort to successfully develop and implement a system for risk-based allocation of inspection resources. Industry stands ready to do its part in the cooperative effort.