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

**RE:    Docket No. FSIS 2006-0028  
       Risk-Based Inspection System**

The American Association of Meat Processors (AAMP) is pleased to submit the following comments on Docket No. FSIS 2006-0028, "Risk-Based Inspection System."

AAMP is an international organization whose members include meat and poultry processors, slaughterers, caterers, food service companies, wholesalers, retailers, suppliers, and consultants to the meat and poultry industry. There are 33 state, regional, and provincial associations of meat processors that are also affiliated with AAMP. Majority of our members are small and very small businesses, with most of being them family-owned and operated.

The American Association of Meat Processors and its members share the common goals with the Food Safety and Inspection Service (FSIS) to improve food safety and reduce the risks to public health. We believe that risk-based inspection (RBI), when based on criteria that adequately and accurately reflect risk, is a logical step in allocating resources to further improve food safety and decrease public health hazards. Key to successful risk-based inspection implementation is 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 are also very important to accomplishing the successful development and implementation of RBI.

One of the greatest challenges related to this type of inspection is defining the criteria used to assess and measure risks associated with federally-inspected establishments. The criteria should be linked using scientific data to the public health consequence. It can be recognized that 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 amongst the federally-inspected plants in terms of size, production volume, types of products, formulations, technologies used, and so forth. Functional, realistic, and scientifically-based criteria for establishing risk must be developed in order for this system to be properly implemented and accepted by industry.

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RBI uses a scientific-based approach to direct limited inspection resources where they are most needed, and at a level proportional to identified risk, in order to reduce to the greatest extent possible the occurrence of foodborne illnesses attributable to meat and poultry products. Key to the success of RBI will be implementation of risk-based regulations and policies, including directives, notices, and rules. Under RBI, FSIS would shift resources toward establishments with products that present high inherent risk and reduce resource expenditures in plants with low inherent risk to reduce the number of illnesses attributed to the consumption of contaminated meat and poultry products.

With so many details still very much in their formative stages, it is extremely difficult to know at this time whether the end result will yield an acceptably accurate measure of relative risk among products and establishments. To complicate the matter further, the Agency provides virtually no clues as to 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. We concur with FSIS that the likelihood of public health enhancements related to inspected meat and poultry products is improved by dedicating FSIS inspection resources to those establishments that have an inherently higher risk of producing contaminated products leading to foodborne illness, while reducing inspection in those establishments presenting lower risk. In reallocating resources with the intent to reduce public health risks, FSIS should not just consider inspection at federally-inspected establishments, it should also take into account the broader food safety continuum; local, state and federal inspection resources should be focused on those areas in the supply chain where the benefits of inspection have the greatest potential for risk reduction.

More details about the values used in the Product Inherent Risk (PIR) algorithm are needed, since it is important for industry stakeholders representing various sized plants to see exactly how the algorithm and its parameters impact the final score. Numerous examples, including algorithm values for specific product/process combinations, would be extremely valuable in helping to determine if the end results of the calculation are practical for use by industry. Examples should be provided for various types of plants producing a variety of products ranging from a single species Ready-To-Eat (RTE) product line to one producing raw and RTE products from multiple species. FSIS must also address the fact that many establishments produce a variety of products with varying risk profiles on a daily basis. This is especially true for AAMP members. We have concerns about the potential unintended consequences of a numerical ranking system as well. For example, should consumers/retailers be concerned about the safety of products coming from establishments with a “predicted” higher inherent risk? Will consumers or customers question the safety of products produced by the lowest rated plants? It must be remembered that regardless of the ranking or number assigned by the Agency to an establishment based on risk, 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, we believe that no form of numerical categorization of inspected establishments should be subject to release under the Freedom of Information Act (FOIA). Additionally, the final risk value assigned to an establishment, which determines the appropriate level of inspection, 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. This is very important to ensure the proper allocation of FSIS’ inspection resources on an ongoing basis.

We believe the Agency should consider a variable weighting for volume depending on the adequacy of an establishment’s risk controls -- greater weight given to volume when establishment risk controls are lax, and lesser weight given to volume for firms with exemplary controls. The issue of volume is of great concern for AAMP members because majority of them are small and very small establishments. No exemplary large volume operation should be excluded from consideration for a reduced level of inspection based solely on volume; nor should any small volume operation with inadequate controls be given a pass solely because of the small volume of product manufactured. Volume needs to be weighted appropriately given the type of product and the establishment’s risk controls.

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Interventions must also be considered as part of the establishment's risk controls. However, because of the vast differences of interventions for small and very small operators, versus those practical for large operations, small establishments may be at a great disadvantage in this area. The Agency needs to handle this appropriately, and determine an acceptable way to incorporate this information so that it does not penalize smaller entities where interventions may be too expensive and less practical to implement. Interventions must be effective, validated tools for preventing foodborne illness and be appropriate for use in the establishment's process. No matter where in the final equation FSIS incorporates interventions, establishments engaged in raw meat grinding should be given credit for purchasing from suppliers that have multiple documented effective interventions. The Agency should reward establishments that effectively, aggressively and consistently conduct internal food safety education programs and are continually improving the execution of their food safety systems. Likewise, those establishments whose risk control worsens will be monitored more closely by FSIS.

We are glad to note the Agency's acknowledgement that not all Noncompliance Records (NRs) relate to food safety. AAMP applauds FSIS' effort to perform NR data analysis to determine which NRs are truly pertinent to predicting adverse food safety outcomes and consider their appropriate weighting. We encourage the Agency to involve all stakeholders in the NR data analysis process. AAMP agrees 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. Many of the proposed measures of establishment risk control are subjective, and are very susceptible to the influence of inconsistencies among inspection program personnel. Although we recognize that FSIS devotes considerable attention to correlation among program personnel, the fact of the matter is that many of the factors identified, e.g., NRs and Food Safety Assessments (FSAs), have been and continue to be subject to inconsistent application and interpretation of existing regulatory requirements. This suggests the need for some means for taking the inconsistencies and subjectivity into consideration when making decisions about resource allocation. For example, a correction factor may be needed to identify inspection personnel that fall outside the norm relative to inspection practices, e.g., for an establishment whose inspector has been frequently overruled on NR appeals or whose EIAO has frequently been overruled in his/her recommendations that NOIEs should be issued. FSAs have value as an audit of a food safety system; however, 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. 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. 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. FSIS must develop a system to monitor and evaluate the applicability of NRs and FSAs when incorporating them into the value of risk control for the establishment.

RBI must not be viewed as another layer of inspection added on top of the existing inspection system. Rather it must be a new, more efficient and appropriate use of resources to enhance food safety for consumers. A properly functioning RBI system will serve to focus attention on food safety and consequently minimize activities that are not supportive of improved food safety goals. This will free up both Agency and industry resources that can be redirected for better purposes – enhanced food safety. The consistency of FSIS inspection on an inspector-by-inspector basis and on an establishment basis should improve under a successful RBI system. The Agency should seek some means to measure this as well. Additionally, it may be worthwhile to implement risk-based inspection as a pilot program in a few areas prior to launching the system for the entire country. This would provide the opportunity to work some of the kinks out of the system and have a better sense of what additional training or information is needed for inspection personnel and industry.

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. The Agency must address the lack of transparency to date in improving the volume variable and defining the impact of interventions; the lack of clarity on

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exactly what were the criteria used for risk ranking of finished products, and the failure to identify the assumptions and uncertainties associated with the risk ranking process. FSIS must provide opportunities to continue their new mantra of "education before regulation" and assist plants who may have a higher associated risk. The notion of being high risk itself should provide plants with an incentive to make improvements, but FSIS needs continue increasing outreach activities and provide additional help when needed. It would also be helpful if the Agency would provide more guidance for small and very small establishments related to the approved or accepted controls that may reduce their overall risk value. This type of specific information may assist in justifying the expense of making changes or improvements because they know for certain that it would reduce their associated risk value. Both the Agency and key stakeholders must reach out to industry to get establishments to take ownership of the idea of Risk-Based Inspection and provide support where necessary under this new system.

AAMP encourages FSIS to continue maintaining a transparent process throughout the development and implementation of RBI. It is critical that all stakeholders are involved and that opportunity for input on the system is available. Thank you for this opportunity to comment on the Risk-Based Inspection System.

Sincerely,



Andrea H. Brown  
Director of Legislative and Regulatory Affairs

cc: Jason Jennings, AAMP President