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October 27, 2006

Ellyn Blumberg
RBI Public Meeting
U.S. Department of Agriculture
Food Safety and Inspection Service
14th St. and Independence Ave, SW
Mail Drop 405 Aerospace
Washington, DC 20250

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

Dear Sir/Madam:

The National Meat Canners Association (NMCA) appreciates the opportunity to comment on the above-referenced notice published by the Food Safety and Inspection Service (FSIS). NMCA, founded in 1923, represents the interests of both domestic and foreign shelf-stable food processors and their suppliers. Effective January 1, 2007 the association will change its name to the Shelf-Stable Food Processors Association to reflect the international nature of our businesses and the fact that our members produce an expanding variety of shelf-stable food products in various packaging formats.

More than thirty-five companies, whose primary or secondary businesses include shelf-stable processed products, comprise the association's membership. Members include companies of all sizes, from regional producers to large multi-national operations. Most of NMCA's members are subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, or both. In fact, the National Meat Canners Association was instrumental in assisting FSIS in the publication of its canning requirements that are currently codified in the *Code of Federal Regulations*. For these reasons, NMCA has a direct interest in the implementation of a risk-based inspection (RBI) system.

NMCA supports the concept of a risk-based inspection system and applauds FSIS for taking the steps necessary to implement such a program. Applying agency resources at establishments producing the highest likelihood of causing human illness, particularly if risk control at those establishments falls short of industry practices and regulatory requirements is a concept that NMCA embraces.

Clarify That All Inspected and Passed Product May Enter Commerce

As a starting point, it is important to understand that all products produced under FSIS inspection and bearing the mark of inspection are safe, wholesome and not adulterated. It is blatantly illegal for FSIS personnel to apply the mark of inspection to products that are unwholesome, adulterated or improperly labeled. Allocation of more inspection resources to certain plants based on the type of product produced in the plant and the degree of control exhibited in the plant must not be interpreted to mean that the products entering commerce pose a risk to human health. This important point should be clearly articulated by FSIS to ensure that all businesses meeting regulatory requirements can market and sell their products without any misconception that their products are unsafe or unwholesome.

Objective and Quantitative Measurements Must be Used

A challenge facing FSIS in implementing RBI is the separation of subjective assessments from objective measures, and using quantitative measures in lieu of qualitative measures. The impact of the agency's ability to address these differences in using RBI is critical to developing and implementing a successful inspection system.

Using an algorithm to categorize establishments in order to allocate resources requires the consideration of as many facts as possible. By using indisputable objective measures FSIS will spend a minimal amount of time defending its categorization of establishments, as well as making clear to 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.

Commercially Sterile Products Are Lowest Risk

FSIS has specifically asked how thermally-processed, commercially sterile products should fit into the range of species/process values that will be used to determine risk. Data clearly show that commercially-sterile, shelf-stable product should be included in the lowest risk category. The controls over canning and the production of other retortable containers are stringent; and the lethality is very conservative. Failures are very rare as supported by historical data; and the incidence of botulinum spores is low such that failures rarely result in toxigenesis preceding spoilage.

Use Positive Data to Evaluate Establishments

FSIS should use “positive data” as well as “negative data” when doing assessments of 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 on industry performance, but also on the agency’s performance in overseeing meat and poultry production. If FSIS considers the production that occurs day after day to be safe and wholesome, it speaks to the high degree of process control that the meat and poultry establishment exhibits and the cooperation between FSIS and industry to control risk.

RBI Concept Should Apply to All Segments of the Food Industry

Although FSIS appears to be focused on the risk-based application of resources in meat and poultry processing establishments, FSIS should consider in its longer term plans the application of RBI over the broader food supply chain from farm to table. With the goal of reducing foodborne illnesses from meat and poultry products, it should be recognized that risk-based allocation of resources may pay greater dividends when the focus is upstream at production or more likely, further downstream at institutions, retail establishments, and restaurants. Only by examining the entire food supply chain will resources ultimately be placed appropriately in order to optimize risk reduction and enhance public health.

Success or Failure of RBI Implementation Must be Measured

It is important for FSIS to indicate what measures are in place to gauge the successful implementation of RBI. Many of these measures exist today, *e.g.*, verification testing data, reduction in foodborne illnesses related 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 at those establishments where inspection resources are increased will be important indicators of success.

FSIS Inspection Performance Must Be Measured

FSIS should emphasize that, along with RBI and the allocation of resources, there will be a renewed effort to focus inspection staff on efforts to educate inspected 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. FSIS could make progress in re-enforcing such a focus by measuring the performance of the inspection staff with input from the establishments. Measures such as consistency of inspection across all inspection staff personnel, the ability to resolve issues in a positive, constructive manner, and the appropriate use of the NR process could be used to gain valuable insights on optimizing the RBI process.

RBI Concept Should Apply to Imported Product

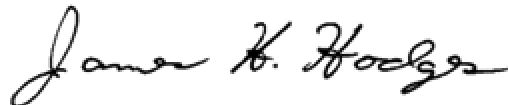
FSIS also needs to ensure that RBI is compatible with international expectations such that implementation of RBI does not adversely affect international trade and the concepts of equivalency with our international trading partners. In that regard, FSIS should re-examine its concept of equivalency, recognizing that foreign inspection agencies may make use of similar risk-based approaches to inspection. This consideration is especially important to prevent unwarranted, costly, and disruptive inspection, sampling, and testing at international borders for microbiological and chemical hazards that are managed through RBI in foreign countries. NMCA recognizes that FSIS has a responsibility to ensure that imported products do not pose food defense risks; but such sampling and testing procedures should remain separate from food safety related sampling and testing that can be managed before shipment across borders through equivalent, if not identical, food safety systems.

Risk Should be Determined by Final Use of Product

When determining the inherent risk of a product that is to be further processed at another establishment, the agency should consider if the product will be further processed and the final use of the product 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 receive the same regulatory scrutiny as the same product produced for direct sale to consumers (*e.g.*, pre-packaged raw ground beef). When establishments are able to demonstrate that product is produced solely for the purpose of further processing, FSIS should take the information into consideration.

NMCA appreciates the opportunity to comment on this important initiative. We would be most pleased to meet with FSIS officials or other interested parties to discuss this issue and provide additional data, if necessary. NMCA also respectfully requests that FSIS accept additional public comment following the issuance of a report being prepared by Resolve, a non-profit organization that FSIS is using to assist with the stakeholder input process. Thank you.

Sincerely,



James H. Hodges
Executive Secretary