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To: Risk Based Inspection
Cc: Kelly, Karlease; Palesano, Bobby; Quick, Bryce; Derfler, Philip; Raymond, Dick -USDA; Masters, Barbara
Subject: RISK BASED INSPECTION (RBI) ADDITIONAL INPUT FROM JOHN MUNSELL.doc

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ADDITIONAL THOUGHTS ON RISK BASED INSPECTION

Submitted by John Munsell on October 27, 2006

I respectfully submit this input to FSIS to consider as the agency develops its Risk Based Inspection (RBI) system. These comments are in addition to those I previously submitted, a copy of which is attached.

Volume of Production has been identified as an integral component in assigning relative risk to each plant, and rightfully so. I suggest that the **Size of Customer Base** is also important. Let me explain. Visualize a large plant which ships product into many states. Such a plant might sell primarily to large scale customers, while avoiding medium and small-sized customers. Relatively speaking, its customer base might be small due to management desire to focus primarily on large scale customers. On the other hand, a medium-sized facility might ship products into fewer states, but to customers of all sizes. Therefore, in spite of lower production volumes, their customer base can be much greater than a plant with higher production.

While customer base information is not currently available to FSIS, inspected facilities could easily produce this information. Plants should not be required to release detailed customer lists, but merely provide a total number of customers to the agency. Admittedly, potential risk to the public increases when a greater number of consumers are exposed to products from a plant. Therefore, FSIS should consider a plant's customer base when assigning relative risks to establishments.

Recalls from small plants might result in notifying a mere handful of customers who were shipped potentially contaminated product. In stark contrast, large national recalls require notification of thousands of customers. OIG's September 2006 Audit Report entitled "*Review of Pathogen Reduction Enforcement Program Sampling Procedures*" makes the statement "*In the risk-based system approach that FSIS is developing, exposure of food safety hazards to the public is related to* ***production volume*** (emphasis added) *and this is where they will place their emphasis*". Fortunately, FSIS has already identified production volume as the focal point of RBI, and I commend the agency for their decision.

The technical papers issued by FSIS on RBI initially suggested volume variables for very small, small and large plants as 1.0, 1.5 and 2.0 respectively. The agency also identified the need to revisit and redesign these three numerical values. Stakeholders at the October 10 & 11 public meetings agreed that these initial numerical values require revision. At the conclusion of the two days of meetings, the suggestion was proffered that a range of 1.0 through 10.0 might be considered. Realizing that one plant kills 5,000 head daily, and another plant kills ten head per week clearly indicates that a 10 to 1 relative categorization does not adequately reflect relative risk to public health. Simultaneously, if the range was set at 1 to 10,000 (which would be true), the higher numbers could skew the finished tabulation with an inordinate weighting being given to production volume. Therefore, I recommend that the volume variable range from .01 to 10.0. This range would not inappropriately adversely impact large volume facilities, while assigning a scientifically correct volume variable to very small plants which often market their products in small rural communities with minimal population.

The previously mentioned September 2006 OIG Audit Report discussed the agency's exclusion of numerous small plants from Salmonella testing. This is partly caused by the agency's use of Salmonella sets which require from 51 – 82 product samples, the sheer number of which eliminate many small plants from FSIS salmonella testing. Very small plants proudly boast of their products' uniqueness and wholesomeness, originating from snail-paced and labor intensive production processes which allow for close visual inspection of meat ingredients. FSIS should consider redesigning its Salmonella testing protocol to redefine "sets" which are much smaller than the existing minimum of 51. This change would return fairness to small plants and provide an opportunity to prove their production of wholesome products, which is currently denied these plants whose low volume production precludes FSIS Salmonella testing. Furthermore, agency access to these future Salmonella test results at small plants would constitute another FSIS management tool to accurately assign risk at these low-volume small plants. In this respect, RBI is akin to HACCP in that it is a living, ever-changing scientific tool which must be flexible to improve its efficacy as new events transpire.

Another issue raised at the public hearings centered on the number of products produced at individual facilities. Some hearing participants questioned if plants should be given "credit" for the complexity of their products. My suggestion is that as product complexity increases, the potential for human error likewise increases. If a particular product has high inherent risk, and requires a complex production scheme, the product should be classified as higher risk.

Pathogens such as Salmonella and E.coli 017:H7 are enteric, i.e. emanating from within animal intestines and residing on dirty hides. In contrast, Lm is environmental. Since the majority of facilities do not slaughter, but their operations are limited to further processing of meat slaughtered at supplier plants, perhaps the **primary** risk faced by the small, downline, further processing non-slaughter plants is pathogen load existing on incoming product. FSIS ability to

scientifically determine accurate relative risk at each plant must address the watershed issue of determining the true risk associated with incoming meat received at the further processing plants. Risk determination is best accomplished via extensive agency-conducted microbial testing of trim at the large supplier establishments. FSIS should consider changing its sampling focus from determining the destination of pathogens to the origin of the pathogens. Pathogens are introduced at the origin of contamination, not the destination.

FSIS is currently authoring new policies which will initiate trim testing at large supplier plants. However, if trim testing is to accurately reflect true **risk** of pathogen-laced trim at the large suppliers, the frequency of FSIS trim tests must be substantial in order to establish a true base line data compilation. As test results reveal a plant's success in consistently producing wholesome meat, frequency of agency testing can be reduced. A plant producing a million pounds or more of trim daily has the potential to sicken a multitude of consumers in dozens of states, quickly. Therefore, the agency must implement ample trim testing at these large volume plants. The lack of substantial sampling prevents the agency from determining true risk, not only at the large supplier plants, but also at the further processing plants whose product wholesomeness primarily depends on process control at supplier plants, over which the small plants have zero control.

Lab results from testing of trim and other products such as ground beef for Salmonella, E.coli et al validate a plant's ability to consistently produce wholesome products. The agency should consider initiating a greater incidence of testing at plants of all sizes. As stated before, many small plants currently exempted from Salmonella testing do NOT slaughter. Since Salmonella is an enteric bacterium, the detection of Salmonella at small downline non-slaughter grinder plants almost always reveals that the small plant is innocently, unwittingly, and legally further processing meat which was previously contaminated at the originating source slaughter plant. Therefore, if FSIS testing detects Salmonella at a small non-slaughter plant, the potential to improve public health is greatly diminished if the agency cannot scientifically determine the true source of contamination. FSIS should mandate that inspectors document the origin of sampled meat at the time of sample collection.

The previously mentioned September 2006 OIG Audit Report was critical of FSIS exempting some plants from testing for E.coli 0157:H7 under the MT03 testing program. Examples of exempted products include meat balls and sausage. The OIG Report stated "*FSIS could not provide scientific support and/or risk assessments to support these exclusions from testing*". I recommend that greatly increased agency microbial testing would provide the needed scientific support for continued exclusion of products from ongoing testing. Testing results provide the scientific justification for changing the incidence and/or existence of testing, and would also provide necessary risk assessments for the agency to assign relative risk required for RBI decisions. While testing doesn't provide answers to all meat inspection problems, it is the best

scientific tool we have to detect pathogens and validates a plant's success or failure in the production of wholesome food.

Stakeholders at the two days of public hearings also spoke of the efficacy of using historical incidence of NR's to aid the agency's assignment of risk at each plant. Rather than FSIS merely using a plant's historical number of NR's, FSIS should consider the number of NR's **per process** as being more meaningful. Plants' historical NR's often describe deficiencies over a wide range of categories, many reflecting innocuous clerical paperwork oversights with little if any connection to the production of safe food. However, if the NR's reflect recurring deficiencies in one particular process (such as jerky manufacturing), FSIS should assign a higher risk variable at that plant until the plant implements corrective actions which are validated to successfully prevent recurrences of the deficiency. Plants lacking recurring NR's in sanitation and **process** production categories should be assigned a smaller risk classification.

The pertinence of company-generated microbial test results was also discussed at the two days of public hearings on RBI. FSIS Notice 54-03 dated 12/16/03 now provides FSIS personnel access to all company test results and monitoring activities. Since the agency currently ascribes importance to company test results, the agency should include these results in its RBI assessment of relative risk. Furthermore, plants generally perform more microbial tests than does the agency, the results of which would provide a more thorough picture of each plant's ongoing success in producing wholesome food. For several years since HACCP's advent, FSIS has allowed plants to validate components of their HACCP plans via results of microbial testing, indicating that the agency considers such test results as being valid. Therefore, these same test results should be included in the agency's assignment of relative risk to each plant.

I am grateful that the agency has invited stakeholders to provide input into the initial development phase of Risk-Based Inspection. I applaud FSIS for their efforts to develop a robust partnership which allows input into this proposal which could have a profound impact on the future assignment of inspection personnel. Agency actions seem to presage FSIS willingness to embrace a bottom up rather than top down method of policy formulations, and as such, the agency is to be commended.

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