S.T.O.P. - Safe Tables Our Priority

America's Voice for Food Safety

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RBI Public Meeting
United States Department of Agriculture
Food Safety and Inspection Service
14th and Independence Avenue, SW
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Washington, DC 20250

Re: Docket Number FSOS-2006-0028: Risk-Based Inspection System

Safe Tables Our Priority (S.T.O.P.) appreciates this opportunity to comment on the two papers that the Food Safety and Inspection Service (FSIS) issued relating to Risk-Based Inspection (RBI). S.T.O.P. is a national, not-for-profit, volunteer health organization dedicated to preventing suffering, illness and death due to foodborne illness by advocating sound public policy, increasing awareness and education, and providing victim assistance. S.T.O.P. was founded in 1993 in the aftermath of the Jack in the Box *E. coli* O157:H7 epidemic from ground beef in California and the Pacific Northwest.

These comments reflect our preliminary thinking on risk-based inspection with the understanding that we may provide additional comments to FSIS at a later date.

Government inspection of meat and poultry products began in 1906 as a response to the appalling conditions in the meat-packing industry. Now, 100 years later, the way our food is grown, processed and sold has drastically changed, creating new problems that did not exist in 1906. Today, foodborne illness caused by pathogenic bacteria is a serious public-health issue. We are faced with a range of new challenges -- from new emerging pathogens to budgetary constraints -- that may require us to redefine our food-inspection system.

Following the Jack in the Box outbreak and the implementation of Hazard Analysis and Critical Control Points (HACCP) systems in the late 1990s, progress was made in reducing foodborne illnesses. However, no significant reductions have occurred over the past few years. As a result, the U.S. Department of Agriculture (USDA) and FSIS are now considering a new approach to meat and poultry inspection at processing plants, one that they believe could lead to further reductions in foodborne illness and death.

S.T.O.P. is troubled by the fact that budget shortfalls may be driving the rush to implement an RBI system in meat and poultry processing plants. Measures aimed at protecting public health and safety should be the government's priority, and therefore must be given all of the resources necessary to ensure adequate protection. Before

adopting an RBI system, USDA and FSIS must prove that it is a demonstrable improvement over the current inspection system. In order to do so, they must take their time and do it right.

General Comments Related to Risk-Based Inspection Initiative

Before addressing the two RBI-related papers prepared by FSIS staff, S.T.O.P. would like to provide some comments about RBI that are general in nature.

S.T.O.P. supports the concept of risk-based inspection

S.T.O.P. supports a scientifically-driven, risk-based inspection system for the nation's food supply. In terms of meat and poultry products, this means that FSIS the government regulatory agency would use robust data to assess risks associated with food production/distribution and then weigh those risks to determine where limited resources can best be directed to prevent contaminated meat and poultry products from entering commerce. S.T.O.P. views RBI as a management tool that would allow FSIS to better allocate its limited resources.

Several elements are critical to the successful development and implementation of an effective, RBI system. Specifically, such a system would:

1. Be transparent through its development and implementation.
2. Be consistent with the governing law.
3. Ensure that *all* processing establishments are subject to at least some minimum level of daily inspection (as well as subject to all requirements related to sanitation, HACCP plans, and microbial testing).
4. Clearly enhance public health as demonstrated through objective assessments.

Developing the data and the infrastructure to support risk-based inspection should be FSIS's highest priority

S.T.O.P. has identified four building blocks critical to building an effective and robust RBI system that protects public health. When one considers meat and poultry inspection, they are (1) comprehensive attribution data; (2) a measure of the prevalence of pathogens in meat and poultry products; (3) enforceable scientific performance standards; and (4) data integrity.

The last of these four building blocks, data integrity, is of the utmost importance in developing a robust RBI system. Without data integrity, the validity of the system will always be in question. To ensure data integrity, the following four elements need to be considered:

Relevance – Will the data address the question that needs to be answered?
Accuracy – Are there sound data collection/management practices and appropriate analysis methods?
Timeliness – Is data shared in a timely manner?
Credibility – Is there sound interpretation and transparency?

S.T.O.P. finds it disturbing that, to date, USDA and the Administration have not demonstrated the existence of, or a commitment to develop, a data collection/management/analysis system necessary to support a robust RBI system.

While S.T.O.P. applauds Undersecretary Raymond's earnest desire to limit the toll that foodborne illness takes on human life, we strongly disagree with his premise that the best way to achieve this goal is to get RBI up and running as soon as possible (as early as the first quarter of 2007). For this reason, Dr. Raymond has concluded that "we must use the data we have." S.T.O.P. believes that this is a fundamentally wrong approach. Instead of rushing to implement an RBI system, Dr. Raymond and FSIS should set as a top priority the development of a state-of-the-art infrastructure capable of collecting and analyzing quality data relevant to determining both product risk and establishment risk.

All data collection methods must be conducted according to strict scientific and statistical codes of practice. As noted by the National Advisory Committee on Meat and Poultry Inspection (NACMPI), it could very likely take two-three years to build the type of infrastructure capable of connecting foodborne illnesses to specific products or predicting emerging food pathogens. S.T.O.P. believes it is worth waiting that long if what results is an RBI system that produces real decreases in the incidence of foodborne disease. Without a solid foundation of reliable, accurate data, a new inspection model could have the unintentional effect of providing less protection to public health.

FSIS should implement RBI as a pilot project and demonstrate that it improves public health before undertaking large-scale implementation

Since RBI would substantially change the current inspection system, FSIS must implement RBI as a pilot program. This pilot program could be in operation while FSIS is building the necessary data and infrastructure discussed above. Given the potential impact on public health, FSIS must do everything it can to minimize any unforeseen negative consequences to consumers. This is best achieved by testing the program in a limited number of plants. Thereby, FSIS can make any necessary adjustments or corrections to its RBI program before instituting it in all meat and poultry processing plants. FSIS must also be prepared to abandon the model if it cannot demonstrate a marked improvement on food safety and public health.

Stakeholders should have been brought into the RBI-development process much earlier

By stating his intention to implement RBI in the first quarter of 2007, Undersecretary Raymond has undermined his assurance that there is "openness and transparency" in the RBI-development process. It has been S.T.O.P.'s understanding that the RESOLVE-led process was simply the beginning – not the end – of the RBI development process, but this is apparently not the case.

S.T.O.P. faults FSIS for not bringing stakeholders into the RBI-development process sooner. FSIS has circumscribed the scope of the discussion of RBI by seeking our input only on the two papers generated by FSIS staff. Stakeholders are being brought into the process after much of the important work – both conceptual and structural – has already been completed.

By contrast, FSIS engaged in a much more inclusive process when it developed the Pathogen Reduction (PR)/HACCP rule in the 1990s. The final PR/HACCP rule was the result of an 18-month process that included: seven information briefings; three scientific and technical conferences; a two-day public hearing; six issue-focused public meetings; a Federal-State conference; and a Food Safety Forum chaired by (then) Secretary of Agriculture Dan Glickman. While S.T.O.P. clearly was not happy with all aspects of the PR/HACCP final rule, and we still have many concerns regarding its implementation, we believe that the process followed in the

development of this rule *was* transparent, and that participation of all interested stakeholders was encouraged and welcomed from the very start.

Because of the important shift that RBI represents for food inspection, along with the outstanding number of issues that still need to be resolved, S.T.O.P. urges the agency to provide interested stakeholders with more opportunities to comment on the various aspects of RBI as it moves towards adoption and implementation of this new system. There are many more details that need to be fleshed out, beginning with some basic requirements, such as a definition of "risk-based inspection" and "predictive indicator," as well as other key terms/concepts.

In addition, we urge the agency to consult closely with its inspection force. Inspectors have the most "hands-on" experience with the current inspection system and could, therefore, provide the agency with useful guidance as it develops an RBI system.

Specific Comments on FSIS Papers

Measuring Product Inherent Risk

Data must determine inherent product risk

Mathematical and statistical models are only as good as the data used to develop them. As discussed above, S.T.O.P. believes that any RBI system must be based on sound data. Unfortunately, FSIS has not yet demonstrated a true commitment to using scientific data to determine inherent product risk. At this point, the data most relevant to inherent product risk – in particular accurate attribution data linking specific illnesses to specific products – is currently unavailable. Therefore, development of this data should be the agency's top priority. Of course, the first step in this process would be to identify data needs and then determine what data is available and what must be obtained.

In September 2006, the USDA Office of Inspector General (OIG) issued an audit report of FSIS's pathogen reduction enforcement program sampling procedures. In the audit, OIG found that some raw ground beef products, such as sausage and meatballs, are excluded from *E. coli* O157:H7 testing. While FSIS justified this decision by stating that these products did not pose a risk that warranted testing, the Agency could not provide any scientific data to support this decision. Therefore, OIG recommended that FSIS perform scientific studies to support its decision to exclude certain raw ground beef products from *E.coli* O157:H7 testing.

FSIS responded by stating that the "NACMCF Response to USDA/FSIS Request for Guidance on Baseline Study Design and Evaluations for Raw Ground Beef Components" provided sufficient guidance to the Agency to justify its decision. However, upon reviewing the NACMCF document, S.T.O.P. could not find any scientific data that supports FSIS' decision to exclude these products. FSIS's response to the OIG Report is troubling and does not bode well for the development of a sound RBI system: if FSIS wishes to implement an effective RBI system, the Agency must use scientific data to make decisions regarding risk.

An expert elicitation cannot act as a replacement for sound data in determining product risk

Knowing that it did not have the necessary data, FSIS undertook an "expert elicitation" to derive a risk-ranking among a defined list of meat and poultry products. An expert elicitation can be useful as a guide for further research and, in some instances, to develop a baseline when no data

is available. However, it is critical that, as soon as possible, data pertaining to the questions targeted in the expert elicitation must be developed in order to get an accurate and objective assessment. Therefore, to create as complete a picture as possible of the risks to human health posed by various meat and poultry products, FSIS must proactively seek data that validates the criteria used to assess risk (i.e. used to establish a risk ranking) and demonstrate their link to public health. As stated by numerous stakeholders, solid attribution data – linking specific pathogens to specific products -- is critical to the successful development of RBI.

Reliance on an expert elicitation is helpful, assuming that this elicitation has been properly designed and executed. This, however, was not the case here. The expert elicitation commissioned by FSIS is flawed for a number of reasons. First, it used predominantly industry and academic experts; there were no public health experts or consumer representatives, even though it is an accepted notion that government should consider the needs and views of all stakeholders when establishing public-health policies. Second, while there were disagreements among the elicitation's experts, FSIS has not provided any information about these disagreements, even though they might have a bearing on a product's final ranking. Third, the range of the scale used to determine risk was not well defined nor was the statistical methodology used in the analysis outlined, making it difficult to assess the results. Therefore, the report's statement that analysis showed agreement among the experts in "regard to the ranking of risk of illness per serving posed by the species/process combinations" is called into question.

Fourth, in the directions for this expert elicitation, the participants were instructed to exclude important "predictive indicators" of known risks/factors associated with foodborne disease. These directions are in direct opposition to the Codex Alimentarius's definition of risk as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food." Specifically, experts were told to ignore the severity of illness caused by particular foodborne pathogens and only consider the risk of illness to a healthy, adult population. S.T.O.P. believes strongly that any determination of risk – be it inherent product risk or establishment risk – must take into account the impact of foodborne pathogens on vulnerable populations (children, the elderly, and people with suppressed immune systems). Any risk determination that does not factor in severity of illness to vulnerable populations is, in our view, fatally flawed. Finally, regardless of the method used to determine the risk ranking, it needs to be validated and then updated on a regular basis. Minimally, in this situation, the expert elicitation should have been reviewed by an independent body, not USDA employees.

S.T.O.P. urges FSIS to go back and revisit the expert elicitation and address the concerns that we have detailed above. It should ask public-health experts to review and comment on the results of the elicitation that was already done, and, as a result, should make any appropriate adjustments. FSIS should also be prepared to undertake another expert elicitation if it is determined that the first elicitation should not be used. Finally, FSIS must, through scientific data, validate the risk ranking and demonstrate its correlation with public-health consequences.

<u>Product volume should not be used as a surrogate for exposure</u>

FSIS sought advice on whether it was appropriate to consider product volume as a surrogate for exposure in determining inherent risk. S.T.O.P. strongly rejects this proposed approach. We join with other stakeholders who urge FSIS to consider product volume as a factor independent of both inherent product risk and establishment risk control. As a result, FSIS's proposed two-dimensional model would be transformed into a three-dimensional model.

Moreover, FSIS must begin to collect and verify data on establishment production levels. The September 2006 OIG report found that the PBIS system does not collect data on production levels or operating schedules. This lack of data has already caused the Agency to erroneously exclude establishments from the sampling frame for *Salmonella* pathogen reduction testing. As stated before, the RBI system will only be as good as the data that supports it.

Measuring Establishment Risk Control

As noted above, reliable data is the foundation of any effective, data-driven system, and we caution the agency not to go forward unless and until it has necessary data relating to establishment risk. In its presentation on establishment risk control, FSIS identified six types of data that should be used in determining the effectiveness of an establishment's risk-control measures: system design, system implementation, pathogen control, in-commerce, enforcement actions, and food defense.

<u>The appropriateness and validity of each establishment's food safety system should play a factor in assessing establishment risk control</u>

S.T.O.P. agrees that, as stated in FSIS's paper, "an establishment's risk control effectiveness is limited by the intrinsic effectiveness of its risk control system's design features." FSIS currently uses food safety assessments (FSA), which are intensive and time-consuming, to evaluate the effectiveness of an establishment's Sanitation Standard Operating Procedures and HACCP system. Because of the importance of an establishment's food safety system, FSIS should establish minimum standards, especially for HACCP plans, which establishments can and do change at will. Furthermore, all plants – regardless of size – should have their HACCP plans verified and validated by FSIS. Currently, due to budget constraints, FSIS is struggling to conduct FSAs and review HACCP plans in a timely manner. Before FSIS can proceed with implementing RBI, the agency must address how to improve this review process.

<u>Proper implementation of an establishment's food safety system is an important aspect of determining establishment risk control</u>

S.T.O.P. agrees with FSIS's statement that "A well-designed and rigorous food safety system does *not* guarantee highly effective risk control in practice. Establishments must also *implement* their systems consistently" (emphasis added). S.T.O.P. maintains that food safety systems must be implemented *properly* as well as consistently in order for the systems to achieve the required food-safety results. FSIS has proposed using certain food-safety related Noncompliance Reports (NRs) as a measure of the effectiveness of an establishment's implementation of its food safety system. While NRs may be relevant in helping to determine establishment risk control, there are several issues that must be addressed in order for NRs to provide an accurate picture of system implementation.

First, FSIS must determine that the NR document, in its current form, provides relevant/objective data to evaluate effective system implementation. Second, as recommended at the Spring 2006 National Advisory Committee on Meat and Poultry Inspection (NACMPI), the agency should undertake a comprehensive review of NRs and establish clear guidelines to determine which ones should be considered in a determination of establishment risk. Apparently, FSIS has only recently begun this analysis. Finally, FSIS must obtain a baseline measurement for system implementation – which is not currently provided by NRs because of the impact that funding shortages have had on the inspectors' abilities to write up complete NRs. For these reasons, we urge the agency not to move ahead with RBI until these issues have been addressed.

Microbial pathogen testing is critical to providing an accurate and objective assessment of establishment risk control

Following the 1993 Jack in the Box *E. coli* outbreak, there was a significant shift in attitudes towards food inspection that culminated in the adoption of the PR/HACCP rule. Under this inspection model, microbial testing plays a crucial role in assessing whether a plant's food safety system is in control by determining whether it is meeting performance standards for *Salmonella* and generic *E. coli.* Microbial testing results showing microbial levels that exceed the standards are indicative of ineffective establishment risk control and require a plant to assess and adjust its program. Unfortunately, while FSIS's Verification Testing Program has provided great benefit, the program has not been implemented consistently.

The September 2006 OIG Report identified several deficiencies that impact the appropriateness of using microbial pathogen testing as a measure of establishment risk control. In addition to finding that FSIS was excluding certain raw ground beef products from *E. coli* O157:H7 testing, the OIG found that the *Salmonella* testing program does not include all required establishments and that FSIS, in fact, excludes small and low-volume establishments from such testing. In response to OIG's recommendation to develop a risk assessment to support the agency's policy for excluding plants from testing, FSIS responded that, under RBI, "the exposure of food safety hazards to the public is related to production volume and this is where they [FSIS] will place their emphasis." FSIS further stated that the agency "does not believe it is a good use of Agency resources to perform the suggested risk assessment." FSIS's decision to exclude small and very small plants from having to conduct *Salmonella* testing is not supported by reliable data and calls into question its approach in developing RBI as a scientific and data-drive system.

While in-commerce findings are relevant, FSIS currently has insufficient data to provide an accurate picture of their connection to establishment risk control

FSIS is proposing to use in-commerce findings such as verifiable consumer public health complaints, Class I and Class II recalls, and certain other findings to assess establishment risk control. While these may represent the current data available to the Agency, they do not provide a complete or accurate picture of establishment risk control. The mere fact that an establishment has not been linked to a recall or public health complaint is not evidence that it has not, in fact, produced and shipped contaminated product. This is because an establishment is not required to notify FSIS when it receives such complaints.

As discussed above, there is a noticeable lack of attribution data, which is identified by nearly all stakeholders as a critical need for implementing a successful RBI system. FSIS's current Consumer Complaint Monitoring System (CCMS) is a passive system that relies on consumers to contact the Agency and report problems. True, this may allow the Agency to identify some hazards in the food supply; however, given its passive nature, it cannot provide the accurate volume of attribution data that is so desperately needed. Furthermore, FSIS has stipulated that only "verifiable" consumer complaints will be used. Given the lack of a food product-tracing system in this country and the ensuing difficulties that most foodborne illness victims have in tracing their illness to a source, the likelihood of obtaining reliable attribution data is further reduced. FSIS must work with other agencies and state and local public health departments to develop a proactive product-tracing system that will provide it with the necessary attribution data.

Food-defense measures are not relevant to a determination of establishment risk

S.T.O.P. agrees with the other stakeholders who believe that it is not appropriate to consider as part of a determination of establishment risk whether an establishment has a food-defense plan. Including such data may result in an underestimation of the risk posed by an establishment.

While FSIS discussed the following two issues as part of the consideration of product risk, we believe that they belong in a discussion of establish risk.

An establishment that processes multiple species or performs multiple processes should be assigned the risk level of the riskiest species or process

S.T.O.P. believes that if an establishment handles or performs multiple species or processes, then that establishment should be assigned the risk level of the highest-risk species or process. The weighted average approach presented in the paper is not one that best protects human health, which is the mission of FSIS.

Interventions used by establishments to reduce risk should be part of measuring establishment risk control and *only* if there is a demonstrable link with reduced foodborne illnesses

There are many different interventions that plants can use to reduce risk. The appropriateness of these interventions is dependent on several factors, such as plant size and type of product being processed. Since these measures would largely be related to an individual establishment risk control, it should not be considered as part of inherent product risk. Furthermore, if FSIS does incorporate interventions into the model for determining establishment risk control, there must be scientific evidence that links specific interventions with reduced foodborne illness. Again, this would require comprehensive attribution data.

Accurate industry data could be used to supplement FSIS data in calculating both establishment risk control and inherent product risk

There was much discussion at the RBI Public Workshop, as well as at earlier meetings of the NACMPI, about using industry data in determining establishment risk (as well as inherent product risk). S.T.O.P. believes that the data collected by establishments could be helpful in providing a more accurate determination of risk. However, there are obstacles to obtaining such data and concerns about its accuracy. Furthermore, we have serious concerns about the type and completeness of data that industry might be willing to share with FSIS. “Cherry-picked” industry data would not provide an accurate or complete picture in helping to determine risk. Therefore, if FSIS were to use industry data, it must ensure that it has data that accurately represents the industry and that does not skew the results. We urge the agency to work with industry to gain access to this data and to establish ways to ensure that industry-provided data is reliable.

Conclusion

As outlined in these comments, S.T.O.P. has significant concerns about the proposed “risk-based” approach to inspection. Nevertheless, we remain committed to working with USDA and FSIS to minimize foodborne illness through more effectiveness food-safety regulation. S.T.O.P. appreciates this opportunity to comment on the papers prepared by FSIS on risk-based inspection,

and we look forward to participating in the development of effective measures that will reduce illnesses and deaths caused by foodborne pathogens.

Respectfully submitted,

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