Consumer Federation of America

November 7, 2006

Ms. Ellyn Blumberg
RBI Public Meeting
United States Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW., Mail Drop 405 Aerospace
Washington, DC 20250

DOCKET NO. FSIS-2006-0028

Dear Ms. Blumberg:

The Consumer Federation of America (CFA) is pleased to offer the following comments on documents and presentations by the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) laying out the Agency's plans to adopt a "more robust risk-based inspection system" and allocate inspection resources according to risk.

CFA is a non-profit association of over 300 organizations, with a combined membership of over 50 million Americans. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Since its founding in 1968, CFA has worked to advance the interest of American consumers through research, education and advocacy. CFA's policy positions are determined by a vote of member representatives. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

A. INTRODUCTION

Before discussing the details of the current plans and papers we wish to make clear to the Agency the factors that form the foundation for our positions. These are the real concerns and hard facts that inform Consumer Federation of America's consideration of the USDA/FSIS proposals to institute a "risk-based system" or "more robust risk-based system" to assure the safety of processed meat and poultry products.

First, CFA member organizations are aware that foodborne illness is a serious public health problem in the U.S. They believe it is unacceptable that each year, 76 million Americans get

sick from foodborne illness, 325,000 are hospitalized and 5,000 die[1]. The CDC acknowledges that these numbers tend to understate the significance of the problem and in addition, the toll from some diseases is increasing.

CFA member organizations are also aware that meat and poultry products present a high risk for foodborne illness. The Center for Science in the Public Interest has compiled from public documents the most complete food attribution data available. CSPI's *Outbreak Alert!* (2005) shows that of outbreaks for which a food product vector can be identified, meat and poultry accounted for 914 outbreaks and 27,431 cases of illnesses. This represents twenty percent of the total outbreaks and cases[2].

Consumers cannot protect themselves from foodborne illness and market forces don't operate effectively to produce safe food. Consumers aren't able to distinguish contaminated products from those that are safe to eat and, if illness strikes, it is extremely difficult to trace an illness back to the original food source.

In the case of meat and poultry safety, U.S. government policy further diminishes market forces as well as efforts by private groups and other governments to assure safety. Every package of meat and poultry is marked with a USDA seal of inspection, conveying to the public, sometimes inappropriately, that all products are equally safe.

While consumers should follow safe food handling techniques when preparing food at home, doing so does not provide complete protection against foodborne illness. Consumers have no way to protect themselves against poor hygiene in commercial kitchens and an increasingly large proportion of our food is prepared by others, either consumed in restaurants or food service settings or taken home for consumption. In short, the realities of the U.S. food production system and the way we live require that government public health agencies and the food industry ensure that food sold in the U.S. is relatively free of disease-causing bacteria and is clean and accurately labeled.

Second, while reducing human illness caused by meat and poultry products is our first concern, most of CFA's member organizations represent low to middle income families who work hard, pay their taxes and want their government to be efficient as well as effective in the operation of its programs. Therefore, when USDA/FSIS is able to demonstrate that its "risk-based" model is more effective in producing food products that are cleaner, safer and less likely to cause foodborne illness, CFA's member organizations will happily support the USDA/FSIS efforts to improve program efficiency.

The following pages comment on the need for USDA/FSIS to adopt a public health model and apply it to the challenge of reducing the risk of foodborne illness from meat and poultry products; the Agency's decision to ignore recommendations from public health experts whose work the Agency funded; the legal issues inherent in shifting to a "risk-based" program without changing a law that never contemplated such actions; the absence of data to support USDA/FSIS' contention that it is pursuing currently a "risk-

[1] Mead, P.S., et al. 1999. Food Related Death and Illness in the United States. *Emerging Infectious Diseases,* 5(5): 607-625.
[2] DeWall, C.S. *Outbreak Alert! Closing the Gaps in Our Federal Food Safety Net*. Center for Science in the Public Interest, November 2005.

based" system and achieving some public health success; the problems in the current approaches to establishing benchmarks for product and establishment risk; and suggestions to USDA/FSIS to improve the process for decision-making.

B. RECOMMENDATIONS MADE BY TWO COMMITTEES OF THE INSTITUTE OF MEDICINE AND NATIONAL RESOURCE COUNCIL PROVIDE THE PUBLIC HEALTH FOUNDATION MISSING FROM CURRENT USDA/FSIS PLANS

Foodborne illness is a human health challenge and is most likely to be met through efforts built on a public health model. While the FSIS describes itself as the public health agency in the USDA, the Agency acknowledges that traditionally it has not employed a public health model in conducting inspection[3]. Because the Agency has limited experience in setting and achieving public health objectives, it occasionally struggles with the challenge.

FSIS Papers on "Risk-based Inspection" Generally Do Not Follow Public Health Oriented Guidelines

We have reviewed a variety of USDA/FSIS papers, including the 2004 Vision statement, speeches by Agency officials, papers prepared for the National Advisory Committee on Meat and Poultry Inspection and presentations for the October 2006 public meeting on risk-based inspection. In reviewing these documents, we could find only one paper on "risk-based inspection" presented to the NACMPI in November 2005 that presented a coherent public health-oriented statement of the USDA/FSIS goals and objectives. In that paper, USDA/FSIS stated that:

> "The agency's public health mission requires it to focus efforts primarily on preventing foodborne illnesses and ensuring a safe food supply."
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> FSIS wants to replace traditional inspection systems for both slaughter and processing operations with a risk-based system that will determine…"the type and intensity of inspection activity at each establishment…through an analytical process that permits inspectors to anticipate problems and focus efforts on those processes and establishments most likely to have control issues and pose a public health risk" (emphasis added).
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> [FSIS] believes that taking resources currently allocated to establishments and products posing minimal health risks and reallocating them to establishments and products that pose the greatest health risks…**should result in a reduction of foodborne illness associated with inspected products…**(and) should permit FSIS to more efficiently allocate resources and respond quickly to all threats to food products under its jurisdiction whether accidental or intentional. (emphasis added)

[3] US Department of Agriculture, Food Safety and Inspection Service, National Advisory Committee on Meat and Poultry Inspection, *Risk Based Inspection Issue Paper*, November, 2005.

> "FSIS recognizes that each step taken toward risk-based inspection must further (improve) public health."
>
> Finally, the Agency acknowledged achieving its goal will require new data systems for the agency to collect, assess and respond to public health data….and will allow FSIS to more fully operate under the traditional public health model of assessment, policy development and assurance[4] (emphasis added).

Other USDA/FSIS papers do not incorporate the public health themes from the NACMPI paper.

More importantly, the Agency has ignored a body of material that it paid to have produced by two committees of the National Academy of Sciences' Institute of Medicine and National Research Council that provide an outline of the principles, objectives and requirements of a public health-based program.

Ensuring Safe Food from Production to Consumption (IOM/NRC 1998) and *Scientific Criteria to Ensure Safe Food* (IOM/NRC 2003) were commissioned by the United States Congress and paid for by funds appropriated to the USDA. USDA/FSIS officials and staff designed the mandate for the Scientific Criteria committee. The roster of members of each committee included scientists, public officials, legal experts and a consumer representative. Notably, both committees included prominent public health scientists.

The two committees had different assignments but both reports include certain basic elements integral to the design of a risk-based food safety system. We include these principles and recommendations here to show that the USDA/FSIS has access to the model it needs and to illustrate how far from the model the current effort is.

> *The overarching purpose of an effective food safety system "is to protect and improve the public health by ensuring that foods meet science-based safety standards." (IOM/NRC 1998)*
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> *The primary objective of a risk-based program should be achieving an established level of health protection. (IOM/NRC 2003)*
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> *A model food safety system will emphasize scientific risk analysis...making it possible to estimate the probability that categories of susceptible persons might acquire illness from eating specific foods, and making it possible to apply resources to those foods or hazards with the highest risk. (IOM/NRC 1998)*
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> *Scientific criteria should be linked to the public health threat they're designed to address, providing a means to measure regulatory effectiveness. This link, currently missing from many regulations, requires integrating data from foodborne surveillance programs and monitoring pathogen contamination in food. (IOM/NRC 2003)*

[4] US Department of Agriculture, Food Safety and Inspection Service, National Advisory Committee on Meat and Poultry Inspection, *Risk Based Inspection Issue Paper,* November, 2005.

Quantitative microbial risk assessment offers the scientific tools to define the most effective solutions for lowering consumer exposure to hazards. The preferred means for developing food safety criteria is a combination of controlled studies and expert opinion. (IOM/NRC 2003)

In order for regulations to be effective, flexible and allow innovation, the regulatory framework should specify results, but not the methods used to achieve these results. (IOM/NRC 2003)

Congress should give regulatory agencies clear authority to establish and base their regulatory efforts on science-based food safety criteria. (IOM/NRC 1998 and 2003)

USDA/FSIS paid for the development of these two reports and developed the questions to be answered by the 2003 committee but has never relied on or even made reference to them subsequently. They are not included as part of the "risk-based" and "more robust risk-based" inspection proposal. Instead, the Agency cites, as foundation for its work, vision statements of USDA political appointees and Agency staff. To develop specifics of the proposals, USDA/FSIS did not refer to the IOM/NRC model or seek assistance from outside experts with experience in developing human health programs. The Agency instead contracted with the same groups it has done business with for many years: organizations with expertise in meat science, animal health, and organizational engineering. It turned to Texas A&M which has a record of landing major FSIS contracts, has close ties to the meat industry and has provided a revolving door for their staff which works on USDA/FSIS contracts, then comes to Washington to lead the contracting agency, then returns to the university to develop more contracts with the Agency.

The Agency cannot develop a responsible plan that offers a reasonable expectation of protecting public health without incorporating the essentials of a public health approach. The Agency cannot expect the public to accept the validity of their efforts when the research and program design come from industry and client universities.

The most meaningful step that USDA/FSIS could take in developing a program that is likely to provide improved public health protection is to abandon the assorted papers it has produced on its own and then use the IOM/NRC reports to create a new plan that is based on the principles, objectives and elements spelled out in them.

C. PROPOSED CHANGES ARE BASED ON FLAWED LOGIC AND DATA

USDA/FSIS insists that it is imperative to move ahead immediately with "risk-based" and "more robust risk-based" inspection in order to protect public health and reduce foodborne illness. Agency leaders express certainty that public health benefits will accrue because USDA/FSIS has implemented some "risk-based" inspection programs, including HACCP and SSOP and these programs have resulted in:

1. Reduced levels of pathogens in meat and poultry products; and

2. Reduction in foodborne illness since adoption of the Pathogen Reduction/HACCP rule.

The officials assert that these changes are proof that the current inspection program is "risk-based," that the program is working, and that implementing a "more robust risk-based system" in meat processing will undoubtedly lead to further reductions in foodborne illness. Therefore, Department officials argue, it is imperative to push ahead with a new program immediately because each day of delay may result in more illness and death.

Our comments below demonstrate that these claims are not supported by the facts and that it would be imprudent to proceed assuming that the current "risk-based inspection" proposals will produce public health benefits.

In a September 27, 2006 speech to the USDA/FSIS Food Safety Education Conference[5], Under Secretary Richard Raymond asserted that USDA/FSIS is already implementing a "risk-based inspection program," telling the participants that:

> 1. USDA/FSIS is currently focusing resources on the products and facilities that pose the greatest risk to public health. Examples of this are the 11-step *Salmonella* initiative announced in February 2006 and the *Listeria monocytogenes* sampling program begun in 2003.
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> 2. USDA/FSIS is now working to create an "even more robust risk-based inspection program...a cost-effective public health program that best serves the American consumer and the meat and poultry industry by preventing human illness and, in turn, protecting those most at-risk from foodborne illnesses." Success requires having the ability to anticipate and quickly respond to food safety challenges "before they negatively affect public health. An enhanced robust risk-based system offers us this ability…to have the flexibility to spend our work hours in a smarter way with more time in the plants that need us there the most to help protect the public's health."

The Under Secretary then stated that:

> *[T]hese risk-based policies, in conjunction with the industry's efforts and our vigorous food safety initiatives, have helped make the meat and poultry supply safer* (emphasis added). The best indicators of this success are those that directly relate to pathogen reduction and public health outcomes. Since 2000, the percentage of regulatory product samples that tested positive for *Listeria monocytogenes* has fallen by 56 percent so that in 2005 only 0.64 percent of regulatory samples taken were positive for this dangerous pathogen
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> The results are even more dramatic for product sampling for *E. coli* O157:H7, which has declined by nearly 80 percent. Only 0.17 percent of FSIS' samples were positive in fiscal year 2005.

[5] Remarks prepared for delivery by Dr. Richard Raymond, USDA Under Secretary for Food Safety, to the 2006 Food Safety Education Conference, September 27, 2006, Denver, Colorado.

Dr. Raymond then told the conference, *"More important than the declines in product sampling numbers is that we're also seeing dramatic declines in the rate of human illness. Comparing human illness data from 2005 with 1998 data, E. coli O157:H7 human illness rates are down 29%, Listeria monocytogenes illness is down 32% and Campylobacter declined 30%* (emphasis added).

Most of these claims are not supported by the facts.

First, Dr Raymond continues USDA's habit of equating reductions in pathogen levels found during regulatory testing with reductions in pathogen levels in all meat and poultry products nationwide. USDA's Office of the Chief Economist, the Office of Inspector General and even some FSIS officials acknowledge that this is statistically inappropriate. There are distinct limitations in the HACCP Verification Testing Program that restrict the range of valid statistical inferences.

In 2003, the USDA Office of the Inspector General noted that the FSIS pathogen sampling program is regulatory in nature, is designed to track establishment performance, is not statistically designed, is based on a sampling base that includes different establishments from year to year and that measures of prevalence represent un-weighted test results from the sampled establishments. The OIG further stated that:

> "FSIS' *E. coli* O157:H7 testing program cannot be used to measure the effectiveness of HACCP on either a company or a nationwide basis. The sampling program, as designed, does not provide scientific, risk-based data to measure the extent of an existing hazard…
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> "The data that is produced does not reflect industry performance because…the sampling plans do not take into account all relevant plant operational or processing factors and samples taken at the plants that are selected are not always representative of the lot of production or final product."[6]

Members of the Safe Food Coalition have repeatedly brought these comments to the attention of USDA/FSIS leadership as well as Under Secretary Raymond and his predecessor and requested that they desist from invoking data that are incorrect and mislead the public.

Second, attempting to directly relate declines in human foodborne illness to reductions in pathogen loads in regulatory samples is fallacious and the data cited are, in some cases, outdated. Arguing that reductions in foodborne pathogens found during regulatory testing are responsible for reductions in foodborne illness is a *post hoc ergo propter hoc* fallacy. This common error in logic assumes that if one event happens after another, then

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[6] USDA Office of the Inspector General Great Plains Region. *Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969),* Report No. 24601-2-KC, September 2003.

the first must be the cause of the second. There are no studies that demonstrate a direct link.

The Congressional Research Service has also questioned the USDA/FSIS' claims of success in reducing foodborne illness. Jean Rawson, in a 2003 brief stated:

> "CDC officials emphasize that several food safety improvements – in addition to HACCP in meat and poultry plants – have been implemented over the same period (e.g., HACCP regulation of fruit and vegetable juices and seafood, and industry adoption of FDA guidelines on *Salmonella* prevention in egg production), and that the data collected have limitations and do not reflect the entire U.S. population. FDA officials state that there may be some connection between HACCP implementation in meat and poultry plants and the decline in foodborne illness, but it likely never will be possible to say exactly how much".[7]

Third, while the specific declines in foodborne illness claimed by Dr. Raymond are correct, he has chosen to cite older and more favorable data. After scoring steady reductions in foodborne illness rates over a period of years, progress on reducing illness caused by several of the pathogens has declined or ground to a halt.

The national objective for reducing foodborne illness is set forth in The Department of Health and Human Services "Healthy People 2010" report. CDC set the baseline for meeting the HP 2010 goals for various foodborne illnesses. CDC's FoodNet began collecting data in 1996 and the CDC uses 1996-1998 as the baseline for showing changes in the rate of foodborne illness. Since foodborne illness rates were very high during the 1996-98 baseline years and have declined rapidly since then, comparing the most recent year's data to the baseline produces a favorable number.

What Dr. Raymond fails to note is that in recent years, with the exception of *E. coli* O157:H7, the rate of pathogen reduction has stalled or has started to creep back up. In the April 13, 2006 Morbidity and Mortality Weekly Report, the CDC noted:

> However, most progress occurred before 2001, with continued small decreases since then. Most of the decline in *Campylobacter* incidence occurred by 2001, with continued small decreases since then. The incidence of *Listeria* infections in 2005 is higher than its lowest point in 2002. Of the five most common *Salmonella* serotypes only Typhimurium has declined with most of the decline occurring by 2001[8].

While USDA continues to cite its *Listeria* rule as contributing to a decline in that serious illness, as noted in the MMWR, there has been no decline since 2002. In fact, USDA and

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[7] Rawson, Jean M., *Meat and Poultry Issues*, CRS Issue Brief for Congress, Congressional Research Service Brief, updated June 6, 2003.

[8] Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, United States, 2005.* April 14, 2006, MMWR, 55(14), 392-395.

FDA ignore the fact that the nation's public health apparatus failed to meet the national health objective of reducing the rate of *Listeria*-related illness to 2.5 per million by 2005. In fact the *Listeriosis* rate is going the wrong way. It increased to 3 per million in 2005[9] over 2.7 in 2004[10].

If USDA/FSIS insists on crediting the Agency's policies for reduced rates of foodborne illness since 1996-1998, the Agency will also have to address the fact that there have been virtually no further reductions in disease caused by *Campylobacter, Listeria monocytogenes* and most serotypes of *Salmonella* since 2001. It is not because we have reached a point where foodborne illness rates are so low they can't be improved. In fact, the CDC has not reduced its estimate of the total number of outbreaks and illnesses[11].

The USDA/FSIS posits the rationale for moving quickly to a "more robust risk-based" inspection on their claims that the current "risk-based" programs have led to reductions in pathogen rates in regulatory sampling, that the regulatory sampling is representative of pathogen rates in all meat and poultry, and that this has in turn translated into reduced rates of foodborne illness caused by pathogens associated with meat and poultry products. Other USDA officials question the regulatory sampling assumptions. The CDC notes that progress against illness has dropped. These facts persuade us that USDA/FSIS lacks sufficient evidence to justify major changes in the inspection program.

Basing a new inspection model on flawed assumptions has often led to unintended negative consequences. In this instance, pursuing a course of action based on spurious numbers may result in increases in foodborne illness.

D. USDA/FSIS LACKS LEGAL AUTHORITY TO ENFORCE CHANGES IN INSPECTION FREQUENCY

The USDA/FSIS insists it can introduce and enforce an effective "risk-based" inspection program without changing the Meat Inspection Act or the Poultry Products Inspection Act. The U.S. Court of Appeals, USDA's legal officers and the scientists and attorneys who studied the issue for the IOM/NRC committees disagree. Two court cases have severely limited the enforcement of USDA's highly touted science-based standards. In the Supreme Beef case, the Court of Appeals ruled USDA could not close permanently a plant that consistently failed to control the presence of the pathogen *Salmonella*. When Nebraska Beef argued that the Federal Meat Inspection Act gave the USDA/FSIS no authority to close a plant that failed to meet its own HACCP or sanitation plans, USDA's general counsel settled the case rather than run the risk of losing again.

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[9] Ibid.

[10] Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, United States, 2004.* April 15, 2005, MMWR, 54(14), 352-356.

[11] Centers for Disease Control and Prevention. *Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 States, United States, 2005.* April 14, 2006, MMWR, 55(14), 392-395.

The IOM/NRC committees agreed that there is nothing in the law that permits allocation of resources according to risk or the use of scientific criteria including performance standards in inspection activities. Both concluded that the law had to be changed to move into a modern inspection system and urged that Congress change the laws.

USDA/FSIS papers indicate that in the new "more robust risk-based system," resources would be allocated so that some companies have more intensive inspection and some have less than they currently experience. It's unlikely any plant will complain about less intensive inspection. However, it is naïve to assume that some plants, subjected to increased levels of inspection, will not protest.

Consider two companies that make similar products and have other similar characteristics. Plant A has a spotless inspection record and the product/establishment matrix suggests it qualifies for reduced inspection under USDA/FSIS' plan. Plant B, down the road, sells the same products but has a spotty compliance record with multiple food safety related NRs. Reviewing the record, USDA/FSIS personnel determine to allocate more inspection resources to Plant B because of the weaker compliance history. Plant B executives realize that their competitor has received a windfall. The reduced level of federal oversight gives the other company more freedom to operate and quite likely, reduces production costs. In essence, the government is granting Plant A a competitive advantage. Plant B's owner is outraged and argues that there is nothing in the Meat Inspection Act that authorizes this kind of discrimination. The owners of Plant B sue the USDA.

If history is a guide, the USDA/FSIS will respond to such a legal challenge by developing additional extensive and complicated "assessments" and "evaluations," resulting in inspectors trying to carry out a weakened version of a "risk-based" regime by requiring inspectors to take on additional labor intensive and financially burdensome paperwork requirements. These extra requirements would only serve as a means for the USDA/FSIS to justify its decision to apply different levels of oversight instead of addressing the problems that increase the risk of foodborne illness.

Ten years ago USDA/FSIS persuaded CFA and other consumer groups to support the Pathogen Reduction/HACCP system, despite the shaky legal foundation for a science-based inspection system. Our support for HACCP was predicated on an assumption that the law permitted not just the institution of *Salmonella* performance standards but the ability to close a plant that consistently failed to demonstrate a commitment and ability to control *Salmonella*. As discussed above, these assumptions proved ill-founded; the USDA/FSIS' ability to enforce the PR/HACCP system has been severely hampered, and the public remains at risk for foodborne illness.

Despite all of the contrary evidence, the Bush Administration continues to insist it is possible to allocate resources according to risk and create an effective system within the limits of the current law. While USDA/FSIS attempts to position its proposals as "science-based," designed to reduce risk and to improve public health, it has almost no data to support those propositions. In the absence of evidence that effective enforcement is possible under the current law, we cannot justify asking our members to support it. We

are quite willing, however, to support USDA in efforts to secure appropriate legal authority.

E. PRODUCT INHERENT RISK CONTROL

Concerns with Expert Elicitation Model

One of the most basic elements of the proposed new "risk-based inspection" proposal is an attempt to define the inherent risk posed by numerous processed meat and poultry products. The USDA/FSIS has developed only one model for determining risk, which had been in preparation for five years and depended entirely on the conclusions drawn from a series of "expert elicitations," i.e., the opinions of experts in the field unencumbered by data. Overwhelmingly, stakeholders at the October public meeting indicated that FSIS' use of its expert elicitation to determine product inherent risk was flawed and needed to be reconsidered.

USDA/FSIS established a series of committees to provide "expert" opinion on relative product risk. The Agency has revealed the membership of only one of those committees. It had 23 members, most of whom are employees or former employees of the food industry and meat scientists, food technologists or food microbiologists from land grant universities. The two public health experts were employees of other U.S. government agencies. No non-government public health scientists, public health officials, medical doctors or consumers were asked to participate. These stakeholders are critical, as they examine product risk from a different and important viewpoint than do industry experts. They also do not have a financial stake in the outcome of the risk ranking process and can therefore provide a more public-oriented perspective.

The Agency did not provide the experts with any data relating foodborne illness to specific foods so each operated from his/her own experience. The Agency asked the expert committee to assume that consumers of these products were healthy adults; an assumption not based in the reality of the actual consumption of these products. Women, children, the elderly and the immune-compromised are at highest risk of foodborne illness and the risk to these consumers should have been taken into account.

In addition, the maximum scores of the risk rankings from the expert elicitation varied widely from 5 to 300,000,000, making any comparison between experts virtually impossible. For that reason it is almost laughable to use a median score in the Inherent Risk algorithm as the Agency is considering. Additionally, it appears the committees never met and members did not test their ideas on one another. The PIR determination was a paperwork exercise. Further, FSIS' presentation of the results of the elicitation was incomplete, in that it did not provide reasons for disagreement among the experts or background material on their conclusions.

Finally, the USDA/FSIS PIR paper notes that the document was "peer reviewed." However, the "peer review" was done by other USDA employees, not by independent

scientists. Nothing has been reviewed for publication in an appropriate peer reviewed journal.

Need for Attribution Data

While expert elicitation can sometimes inform a process, the development of a "risk-based inspection system" cannot rely on experts alone. In order to be able to accurately determine product and establishment risk, such a system must be based on solid scientific data. This should include attribution data, so that the Agency can link particular foods with the severity of illness they cause. Almost universally, participants at the October public meeting stressed the importance of attribution data in order to implement a risk-based inspection system. The two IOM/NRC reports previously mentioned have also emphasized the need for food attribution data.

Currently, however, the only type of attribution data we can access is outbreak data, which is under-representative. If it indeed wants to establish a meaningful base for a public health program, USDA/FSIS needs to slow down its implementation process until it has useable data that can support its risk ranking categories. This means that certain elements need to be in place, such as a comprehensive, verifiable traceability system and a modernized computer infrastructure system capable of collecting, analyzing and sharing data throughout the Agency. Without such data, FSIS will create a system that does not accurately reflect the true risk to the population and may endanger the public's health, particularly those most at risk for foodborne illness.

Although USDA/FSIS describes this proposed move to a "more robust risk-based inspection" as "science-based," it is clear that the Agency was unable or unwilling to take the time or devote the resources required to develop the data to make possible a thorough and detailed calculation of risk. The agency did not develop new data to help define inherent risk and made no effort to integrate existing food attribution data in its model despite the fact that both the IOM/NRC reports and USDA/FSIS staff have noted that expert elicitation is the least reliable way to make these estimates.

A close reading of the PIR paper suggests that the USDA/FSIS approach to determining inherent risk may have been constrained by lack of funding and some need to rush to judgment. The PIR paper notes the difficulty of covering the cost of contracts with the "experts" and may be responsible for the fact that the expert committees never met. It may also be responsible for the fact that the so-called "peer review" of the elicitation findings was done by USDA employees, not outside experts.

If the Agency had trouble covering these relatively minor costs it may be reasonable to assume cost (and perhaps time) were a factor in deciding neither to undertake a risk assessment nor to gather the best available food attribution data. Although these methods are preferred to expert elicitation, they would have required an investment of money and time the Agency seemed unwilling to support.

Thus, although the proposal to move to "more robust risk-based inspection" in processing is cited as a major Agency initiative and one that is absolutely essential to protecting the

public health, it is clear that the USDA/FSIS did not find it important enough to develop the data needed to back their assumption that the proposed changes would truly protect human health.

CFA urges FSIS to take the time necessary to acquire meaningful food attribution data and incorporate it in any determination of inherent risk. It should discard the findings of the previous multiple expert committees and the next time it seeks to balance other data with expert opinion, it should include input from medical doctors, academicians from public health universities, public health officials and consumer groups.

F. ESTABLISHMENT RISK CONTROL

FSIS documents indicate that "inherent risk of an establishment" will be a pillar of its "risk-based inspection" proposal. The Agency has outlined five elements of establishment risk control that it considers essential to a determination of establishment risk. While most of these elements could be considered useful in measuring how an establishment is controlling risk, CFA has a number of concerns about how USDA/FSIS intends to measure each element.

Food Defense Activities: At the October public meeting both industry and consumer groups told Agency officials that it is inappropriate to incorporate Food Defense activities in the Agency's risk control determination. Food Defense should either not be included or given a minimal amount of significance.

Food Safety System Design: This is a critical element of risk control in an establishment, but USDA/FSIS does not have a satisfactory method to measure it. At the October public meeting, Dr. Masters said that Food Safety Assessments (FSA) would be the primary mechanism used by the Agency to determine whether a plant's food safety system design is satisfactory. However, FSAs are not conducted frequently enough to allow them to be used as an ongoing indicator of establishment risk control. They occur, on average, every three years. Some plants change their product mix weekly, triggering changes in HACCP and SSOP plans, and major changes can occur in plants over a three year period. A plant could complete an FSA one day, change its product mix the next and, because of the infrequent nature of FSAs, USDA/FSIS would have no reasonable measure of the risk in the plant for the next three years. FSAs are also expensive and time consuming. It is not likely that USDA/FSIS can acquire staff resources to conduct them frequently enough to make them a useful measure of establishment risk control.

Aside from FSAs, the Agency cites its rule to control *Listeria monocytogenes* in ready-to-eat meat and poultry products (9 CFR 430) as an example of its ability to assess a plant's food safety system design and successfully control pathogens. CFA has documented serious weaknesses in this regulation in our 2005 report, *NOT Ready to Eat*[12]. The report

[12] Tucker-Foreman, C., Waldrop, C. "NOT Ready to Eat: How the Meat and Poultry Industry Weakened Efforts to Reduce Listeria Food Poisoning." December 2004, Consumer Federation of America. Retrieved from: http://www.consumerfed.org/pdfs/CFA_Not_Ready_to_Eat.PDF.

demonstrated how the *Listeria* alternatives considered by USDA/FSIS were based less on measures to protect public health and ensure reduction in pathogen contamination and more on industry pressure to develop less stringent regulation than originally proposed.

The RTE *Lm* control rule is not an adequate measure of whether a plant is actually controlling *Lm* in finished products and certainly not a model for future efforts to measure a plant's food safety system effectiveness. USDA/FSIS developed a risk assessment for controlling *Lm* that specifically excluded any consideration of the potential health benefits that might be gained by requiring companies, in addition to testing the environment and food contact surfaces for *Listeria spp,* to test finished products for *Lm* and report those findings to USDA officials.

Under the current program no plant has to demonstrate regularly that its *Listeria* program actually assures that final ready-to-eat products are free from this deadly pathogen. USDA/FSIS regulatory testing for *Lm* is infrequent and there is no scientific basis for the determination to test more frequently in plants without controls. It is quite possible that a plant with controls regularly produces RTE products that are adulterated with *Lm*. USDA/FSIS cannot prove that its system works because the Agency will not collect itself or require industry to submit data to demonstrate different levels of end product contamination in plants with controls, show there is less *Lm* in finished products now than before the rule, or show that testing final products for *Lm* frequently, in addition to the existing controls, would not reduce levels of contamination.

USDA/FSIS officials often cite the reductions in *Listeria*-related disease as evidence that the program is effective. As discussed elsewhere, the Agency is comparing the average rate from the beginning of FoodNet collection (1996-1998) to FoodNet data for 2005. That comparison shows a marked declined. However, since USDA/FSIS repeatedly cites the *Lm* rule as a marked improvement over previous *Lm* control efforts, it is reasonable to ask what the experience has been since it was first announced and begun to be implemented. Again, as noted elsewhere in these comments, the occurrence of *Listeria*-related food poisoning remains the same or higher today than it was in 2002. In 2005, the rate was 3 cases per million population. This means that the U.S. government failed to meet the national health objective for reducing the rate of *Listeria* foodborne illness. That objective was to reach 2.5 cases per million by the end of last year. At this point *Listeria* control efforts cannot be deemed successful and should not be used as a model for any future program.

System Implementation: This is an important element of establishment risk control as well. However, the USDA/FSIS does not have an adequate plan for determining how to measure the effectiveness of a plant's implementation of its HACCP and SSOP programs. The Agency acknowledges that the current system for determining when a noncompliance record (NR) should be issued is not related to the degree of risk involved. The December 2005 paper presented by the Industry Risk Based Inspection Consortium has made clear they will not tolerate use of the current system to measure anything. FSIS has pledged to review its NR system to determine which NRs might be appropriate for use in determining risk. However, the Agency has no data to indicate whether the current system for issuing NRs is effective in reducing the number of noncompliances or whether it results in end products with less pathogen contamination.

Current financial realities have impacted the Agency's ability to fully staff all of its inspection positions. It takes time to assess and then write up NRs. Overworked inspectors may be unable to spend the time necessary to utilize the NR system to reflect plant performance. Consequently, it is quite possible that NRs are not being written or documented to the same extent as they would be if the Agency was fully staffed. It would be unwise to rely on the current NR system as an indicator of establishment process control.

If the agency intends to make NRs part of a "risk-based" system it must collect the data to evaluate effectiveness of the current system and to build and test a new system. The Agency needs to know how relevant the process and the categories of NRs are to reducing foodborne illness. For example, if no NRs were issued, would products coming out of a plant be more or less contaminated with disease causing organisms? What evidence is there that a rigorous application of NRs results in production of products that are less frequently contaminated and have a lower pathogen load?

If USDA/FSIS decides to research these issues, develop a system to gather this data, and submit it for peer review, CFA will comment on those results. However, we will oppose any use of NRs to reduce inspection intensity until such research is conducted and a pilot test in a variety of active plants demonstrates that the end result is lowered risk as evidenced by lower levels of pathogen contamination.

Pathogen Control: This is another critical element of establishment risk control, but the Agency does not do verification testing for pathogen control in all plants. Approximately 25% of processing plants are not subject to FSIS sampling verification. The Agency has not said how it determines the level of pathogen control in plants where it never checks pathogen levels. In September 2006, the OIG found that "a significant number of establishments were excluded from the *Salmonella* sampling database[13]." In addition, the OIG noted that "exclusions continue to exist" in the Agency's testing program for *E. coli* O157:H7 and that "because of these exclusions, there is a reduced level of assurance that products produced at these establishments will be free of dangerous pathogens[14]." USDA/FSIS was unable to provide data or test results to substantiate its decisions in these areas. This gap in the Agency's data makes it very difficult to be able to accurately and scientifically apply a plant's pathogen control system into the measurement of establishment risk.

In order to more fully determine risk within an establishment in terms of its control of pathogens, USDA/FSIS should seek to establish enforceable pathogen reduction performance standards. By requiring performance standards for the control of pathogens in meat and poultry products, USDA/FSIS would be able to more accurately determine, through regular monitoring and testing, whether a plant was meeting that standard and eliminating risk in its products. This would ensure the lowest level of contamination that is reasonably achievable with current technology and practices. These standards should

[13] USDA Office of the Inspector General Midwest Region. *Review of Pathogen Reduction Enforcement Program Sampling Procedures,* Report No. 24601-0007-Ch, September 2006.
[14] USDA Office of the Inspector General Midwest Region. *Review of Pathogen Reduction Enforcement Program Sampling Procedures,* Report No. 24601-0007-Ch, September 2006.

be revised every three years to continue to reduce the risk to the public of foodborne illness. Without such standards, the Agency cannot effectively work to drive down the prevalence of foodborne pathogens in the meat and poultry supply and efforts at pathogen control cannot be systematically monitored.

In-Commerce Findings and Enforcement Actions: These elements may have some relevancy to an establishment's ability to control risk. However, this information is not collected in a systematic way. It is hard to see how an undifferentiated mass of communications is relevant to overall establish risk control. We have a sense that this element has been thrown into the mix just because it is there and the Agency needs more elements to consider.

G. CONCERNS ABOUT HISTORY, PROCESS AND FUTURE DIRECTION

CFA applauds the USDA/FSIS decision to develop its plans for "risk-based inspection" in meat and poultry processing in an open and transparent manner. We understand that an agency that does not have a long history of trying to involve all stakeholders or an established process for engaging outsiders may be unfamiliar and uncomfortable with the need to be open to sharing information and accepting suggestions. It would not be surprising if the Agency is uncertain about the wisdom of an open process. CFA hopes the Agency will not abandon the effort to encourage active public participation early in the development of this and other policies. While doing so may mean being asked to come up with information before the Agency is ready or respond to questions the Agency never anticipated at all, by and large it is easier to address the unanticipated early in the process rather than later.

As CFA has tried to participate in the process, we have been confronted with a number of troubling issues. Most of them are discussed at length elsewhere in these comments. In this section we will raise our concerns about history, process, and anticipated future directions.

Confusion About Terms and Timeline

We need the Agency to provide specific definitions of terms. We do not know how USDA/FSIS defines "risk-based inspection" or "more robust risk-based inspection," what the differences are in these two programs and how they differ from other elements of inspection. CFA would like to know which parts of the FSIS program falls into which column.

CFA would also like to know when the effort to create the "risk-based" and "more robust risk-based inspection" programs began. FSIS Senior Press Officer Steven Cohen told *Food Chemical News* that the Agency first presented a plan for "risk-based inspection" to Congress in March 2001. He referred the public to a report submitted to Congress and published on USDA's website. That report does indeed discuss "risk-based inspection" and provides details on the development of the contracts with the Research Triangle

Institute and Texas A&M University to develop product inherent risk determinations. It also discusses a public meeting to be held in 2001.

The 2001 report, however, stated the basic rationale for "risk-based inspection" as reducing inspector shortages without increasing the inspection workforce. CFA has been told that the current program proposal is specifically not envisioned as reducing staff levels, but we do not know when or why reduction of inspector shortages was dropped from the proposal. Should we assume that the current effort will not consider the impact on staffing levels and will not seek to avoid inspector shortages? FSIS followed the March 2001 report to Congress with a public meeting to further explore anticipated changes. USDA/FSIS presented a five year-plan that said "risk-based inspection" and all other elements of the Agency's work would follow the classic risk analysis model of risk assessment, risk management and risk communication. However, the current process does not seem to be applying a risk analysis model and we do not know when or why the Agency decided not to use risk analysis to build the current iteration of its program.

We are unable to integrate Steven Cohen's comment and the October 2001 plan with comments made at the October 2006 public meeting. At the October 2006 meeting we understood Dr. Masters to say that the 2001 "risk-based" inspection plan is not related to the current "risk-based" inspection plan. We would like to know if that is the case, why that decision was made and what the differences are between the 2001 plan and the current plan. We'd like to know why the FSIS information officer believed that the current effort is the same as the one described in 2001.

We are also confused about how far the Agency has gone in formulating its "risk-based" and "more robust risk-based" inspection programs. At the October public meeting, the Agency emphasized that it was in the beginning stages of the process. Dr. Masters stated that the Agency "is not here to unveil a finished product[15]." Deputy Executive Associate Bobby Palesano said, "You think we have the answers. We are the ones asking the questions[16]."

However, both the 2001 report to Congress and the July 19, 2006 paper on product inherent risk indicate that the efforts to define inherent product risk and to assign inspection resources based on risk began five years ago. By March 2001 the contracts with Texas A&M and RTI had been signed. The Agency knew it was going to use expert elicitation to assess risk. These facts seem to reflect that the Agency is not in the very early stages of this project.

Further evidence that the project is well on its way is the timeline Dr. Raymond seems to be following. At one point he indicated the program would be launched in January 2007. More recently he has referred to "the first quarter of 2007." He has repeatedly stated that he wants a "risk-based inspection" program to be completely operational by the time he leaves the Department of Agriculture in 2008, two years from now. Two years is not a realistic time frame for a program starting from scratch.

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[15] Sugarman, C. "Risk based inspection workshop draws controversy and consensus." *Food Chemical News,* Vol. 48, No. 36. October 16, 2006.
[16] Ibid.

These conflicting comments and timeframes can only create uncertainty and distrust as to the Agency's intentions.

Recommendations

The Agency should provide a document that defines "risk-based" and "more robust risk-based," describes the purpose and goals of the proposed program and an outline of the history and scope of the project and a legal memo on what statutory provisions justify the actions. The document should, as well, indicate what regulatory tools the Agency intends to use to implement its new program. Will it use rulemaking or seek to accomplish it goals by directive to inspectors and why has it chosen that course? Were other options considered and, if so, why did the Agency opt for this plan?

It would be helpful to include a timeline that shows what the Agency seeks to accomplish and what data support the plan, specific actions that must be undertaken to result in appropriate directives to its inspection force, dates for the completion of each major step and the final plan, and at what points and in what manner it expects to provide opportunities for public comment and public participation.

H. TESTING OF ANY NEW MODEL IS ESSENTIAL

As the Agency continues to develop its "risk-based inspection" model, it needs to seriously consider the potential for unintended consequences. Despite all the planning in the world, not every single detail will be addressed and certain ramifications of decisions are then discovered during the implementation phase. FSIS has said that the "risk-based inspection system" is being implemented to protect the public health. For that reason, we highly recommend that the Agency test their "risk-based inspection" model prior to implementing it across the country. Ideally, the Agency would perform a trial run side-by-side with the current system to help determine whether the "risk-based inspection" model is superior to the current inspection system. That way, the Agency could absorb lessons learned on a much smaller scale with a smaller impact on the public before fully implementing a new system.

Respectfully submitted,

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