Consumer Federation of America

COMMENTS ON THE FOOD SAFETY AND INSPECTION SERVICE PROPOSALS TO MAKE BASIC CHANGES IN PROCESSING AND SLAUGHTER INSPECTION
Submitted by
CONSUMER FEDERATION OF AMERICA
RE: Docket No. FSIS-2008-0003
March 24, 2008

Consumer Federation of America[1] submits the following comments on what the Food Safety and Inspection Service has chosen to label a "public health risk-based inspection system." The comments address both the Technical Plan and Appendices.

Consumers have a right to expect that meat and poultry products marked "USDA Inspected..." are clean, free from high levels of pathogens and reasonably likely not to make us or our families sick. American consumers, as taxpayers, invest a billion dollars a year to support meat and poultry inspection. Meat and poultry products enjoy a unique advantage in the market place. They are the only products that go to consumers with a mark of endorsement by the U.S. government. This unique benefit provided to industry imposes on USDA a unique responsibility to consumers to assure that public safety, not industry or Agency convenience is the

[1] Consumer Federation of America 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 vote of member representatives at board meetings and the annual meeting.

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.

primary consideration in USDA action. USDA is not meeting that obligation now and the proposed papers do not alter that situation.

The FSIS proposals discussed at the NACMPI meeting are neither "public health" nor "risk" based.

In the several hundred pages of information presented to the NACMPI, the FSIS seeks to garner public support for proposed changes in meat and poultry inspection by calling them "public health-based" and "risk-based." The Agency asserts that adopting its proposals will result in improvements in public health.

However, CFA cannot find in the supporting documents, either justification for the program changes or evidence the changes have any basis in public health protection. The Agency has no meaningful data to support the assertion that its plans will meet any public health objective.

The actual changes proposed in inspection procedures are not closely related to the documents that are offered to support the public health benefits of the changes. For the most part the changes involve decisions to redistribution of inspectors among and within plants. In this respect, the so-called public health based proposals are nothing more than slight revisions of changes USDA has proposed in one form or another since 1973, all made for the primary purposes of curtailing the growth of the inspection staff and freeing industry to speed up production lines.

The processing proposals use the same language that USDA proposed to Congress in the early 1980s and that was adopted in the Processed Products Inspection Improvement Act of 1986. That discredited law, slipped through Congress with no hearings or debate, expired without having been implemented.

The FSIS cites two NAS studies from the early 1980s in support of its so-called "risk-based" system but, after 25 years, still has no data to support the changes.

The FSIS, notably, does not cite nor endorse the NAS study it paid for in 2003 that recommended USDA seek and Congress enact legislation giving the FSIS authority to set and enforce mandatory food safety criteria, including pathogen performance standards.

CFA believes that the proposed plans, because they lack a meaningful relationship to efforts to improve health protection, present a large

risk of unintended negative consequences, most likely an increase in rates of foodborne illness in the U.S.

CFA urges USDA to take steps to reduce the high toll of foodborne illness and death resulting from contaminated meat and poultry, by committing the time and resources and leadership necessary to develop a scientific data base capable of identifying and achieving specific public health objectives and then building a new inspection program based on the risk reduction data.

CFA will support changes in meat and poultry inspection that can be shown to reduce both the presence and the number of foodborne pathogens on raw and processed meat and poultry products sold at retail or to food service operators.

CFA opposes changes to the inspection systems until such time that USDA is able to demonstrate that the changes can be directly related to a reduction in the presence of pathogens on products sold at retail.

CFA opposes efforts that have been developed based on political and personal timetables rather than public health data, that seek to stretch existing data to inappropriate uses and conclusions, that are driven by industry desire to speed production lines regardless of human health consequences and that foster the continuation of the notoriously outmoded and irrational meat and poultry inspection program.

The FSIS prepared the papers for presentation to the National Advisory Committee on Meat and Poultry Inspection. During the two day NACMPI meeting members of the panel expressed concern about integrity of the FSIS claim that the proposals serve a public health goal.

CFA strongly recommends that the FSIS pay particular attention to the recommendations, adopted by the NACMPI urging the Agency to:

- Refrain from referring to the programs in development as "public health based" until it has more robust data including a true national prevalence number as well as enumeration and serotype information.
- Not move ahead with any new inspection system until it has acquired more robust data on the relationship between specific foods and illnesses attributed to particular pathogens

• Consult with the CDC on the best way to factor into the database the impact of sporadic cases of illness

• Develop enough *Campylobacter* data to establish a performance standard.

• Seek assistance from the NACMCF to establish appropriate data to be used in determining risk and ways to avoid methodological problems in using limited data to develop inspection levels.

The papers presented to the NACMPI continue USDA's inappropriate claims about its *Salmonella* data and CFA, again, urges the FSIS to cease:

•Misusing the *Salmonella* verification data as representing the national prevalence of contamination,

•Asserting that the *Salmonella* performance standard is public-health based, and

•Attempting to mislead the public by arguing that the fact that most plants are able to meet the *Salmonella* performance standard is responsible for a reduction in some types of foodborne illness.

Among the issues the FSIS must address in developing a public health based program are the following:

CFA urges the FSIS to stop relying on misuse of the *Salmonella* verification testing data to justify its programs and stop making inappropriate claims about what the *Salmonella* data represent.

The FSIS continues to cite data from verification testing as though it represents a national prevalence the data represent only what happened in one plant on one day—the day the tests were taken. The hazard identification in the risk assessment begins by citing the summary of data from the FSIS routine testing program.

The FSIS exposure assessment states "*Prevalence* of *Salmonella* on young chickens in slaughter establishments was determined using data from the FSIS microbiological baseline data collection from the years 2003 through 2005. (Draft Risk Assessment, Nov. 2007) (emphasis added)

The Office of Inspector General and the National Advisory Committee on Microbiological Contamination have both told THE FSIS it cannot legitimately cite the data as national prevalence data. (National Advisory Committee on Microbiological Criteria for Food, Response to

Questions Posed by the FSIS Regarding Performance Standards for Food (Broilers), Feb. 14, 2004, page 12.)

The *Salmonella* performance standard is not a public health based standard but is a reflection of the industry's capacity to control *Salmonella* a dozen years ago. It is an industry performance based standard, a reflection of industry's ability to control process. The HACCP regulation established the *Salmonella* standard at a number that half of the industry was able to achieve. There were no data then or now to relate the performance standard to a public health objective.

Further, the *Salmonella* standard has not been updated since the baseline data for the HACCP regulation 12 years ago. It has in fact become an obstacle to improving industry process control. Because it has not been changed it permits slackers to continue to do just enough to meet the industry "average" of 12 years ago.

Even if the *Salmonella* data represented the prevalence of carcasses contaminated with *Salmonella*, it would not be an accurate picture of the human health risk from *Salmonella* because the performance standard only reflects the number of carcasses that are contaminated, not the level of contamination on each carcass.

At some level the risk of illness is related to the dose of *Salmonella*, the number of organisms present on a carcass. The FSIS acknowledges that it has no enumeration data at all. Page 45 of the draft risk assessment speaks optimistically that these data will be forthcoming, some day, but the Agency proposes to begin the program without having any idea of the level of *Salmonella* contamination on poultry. In the absence of the most basic public health related data, the Agency cannot justify referring to this as a public health based program.

The FSIS continues to assert that reductions in levels of *Salmonella* found in verification testing, compared to the beginning of the HACCP program, are directly related to reductions in foodborne illness.

While *Salmonella* related illnesses declined immediately after HACCP was introduced, the number of illnesses per hundred thousand population have not continued to decline. The CDC FoodNet Report for 2006 stated that *Salmonella* and E. coli O157:H7 are, despite initial declines after HACCP near the baseline levels. If there is a relationship between the *Salmonella* performance standard and the rate of

Salmonellosis cases, it would appear to be going in the wrong direction.

CFA stresses that the FSIS must not move forward on any program it calls, "public health based" without fully integrating the risk from *Campylobacter* and implementing programs specifically designed to control it.

The FSIS plans for processing and slaughter inspection changes completely ignore the risk to human health created by *Campylobacter.*

The FSIS (citing Mead, et al, 1999) acknowledges that *Campylobacter* is the most common cause (47%) of bacterial foodborne illness in the U.S. but ignores the pathogen in its risk assessment and program structure. The CDC reports that *Campylobacter* is associated with 2 million cases of foodborne illness each year, twice as many as *Salmonella*. In its FoodNet Report for 2006, the CDC stated that progress in reducing the number of cases of *Campylobacteriosis* has stalled, with no improvement since 2001.

Poultry is the food most commonly associated with *Campylobacter* contamination.

Yet the FSIS in developing a program that it claims is related to protecting public health, has constructed a risk assessment that excluded any consideration of illness caused by *Campylobacter*, has designed a program that has no steps to control *Campylobacter,* and has established no performance standard for *Campylobacter*.

The FSIS says it will establish performance standards for *Campylobacter* at some future time but it is not likely to be soon. The HACCP program used *Salmonella* as the standard for process control because when the program was first adopted, the Agency thought *Salmonella* was the most common cause of bacterial foodborne illness. At least as early as 2000, the FSIS learned that *Campylobacter* caused more illness than *Salmonella*. At one point the Agency had a major program underway to address *Campylobacter* concerns and set a performance standard but the Agency has never taken action to implement controls. The Agency began promising to collect and report *Campylobacter* baseline data ten years ago and still does not have it. It tried to collect the data in 2001 but stopped. In 2004, the NACMCF told the Agency how to do the collection. The FSIS made another effort in 2005 and sent out instructions to inspectors for collecting the data. The instructions were withdrawn with no public explanation as to

why. New instructions were sent out in May of 2007. It is now 10 months later and the Agency can say only that the data are being collected not when it will have them complete. The Agency also promises a performance standard for *Campylobacter* but does not state when it will be established, nor how it will be shaped to be a public health based rather than an industry capability standard.

Because it has not been able to manage an attack on this very serious pathogen, the FSIS has constructed a program that ignores it. There is no justification for proposing something called a public health-based" program without having mechanisms for controlling *Campylobacter.*

The proposed programs for poultry slaughter relate only to generic e. coli and *Salmonella* control. Controlling *Salmonella* does not assure that *Campylobacter* will be controlled. [2]

The FSIS proposes to permit plants to increase their line speeds if they can show control of *Salmonella* but give no consideration to the illnesses that may be caused if these actions increase the levels of *Campylobacter.*

The decision not to include consideration of illnesses caused by *Campylobacter* is a reflection of the FSIS's imperative to develop and implement a program before it has adequate data on which to base it.

While Appendix A lists five ways to develop food attribution data, the FSIS decided to dismiss the more reliable methods of allocating risks--CDC case control studies, risk assessments for individual foods and pathogen serotyping --because those methods required time and money. Instead the Agency relied on the less precise options—outbreak data, specifically CSPI's *Outbreak Alert*, and the 2007 FSIS expert elicitation. The methods were less reliable but had at least two advantages. *Outbreak Alert* already existed and it gave the FSIS an opportunity to associate its program with the work of a respected consumer organization. [3]

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[2] Newell, Diane and Wagenaar, Jaap, Poultry Infections and Their Control at the Farm Level, in *Campylobacter,* 2nd Ed., 2000 American Society for Microbiology, Washington, D.C., Murphy, C., Carroll, C. and Jordan, K, Environmental Survival Mechanisms of the Foodborne Pathogen *Campylobacter jejuni,* Journal of Applied Microbiology 100, (2006) 623-32

[3] Based on public comments by leaders of USDA, it appears there was a second reason for adopting *Outbreak Alert.* The study reports data in a manner that tends to diminish the illnesses associated with products regulated by the FSIS and emphasize

Both of these methods have fatal flaws that make them an inappropriate base for a public health based decision with regard to changes in meat and poultry processing and slaughter.

Outbreak data do not provide an adequate picture of the risk of foodborne illness. The CDC states that most cases of foodborne illness are the result of sporadic (individual) cases, not outbreaks. CSPI's *Outbreak Alert* acknowledges this. However the CSPI data cover only those illnesses associated with outbreaks (two or more illnesses traced to the same product). CSPI does this because both CDC and health departments report outbreak data, not sporadic cases.

When CSPI refers to the number of illnesses caused by a particular food, it is referring only to illnesses associated with an outbreak, not the total number of illnesses. While CSPI's data are useful, they give an extremely inaccurate picture of the total burden of foodborne illness in the U.S. because the distribution of total number of illnesses is not the same as the distribution of illnesses attributable to outbreaks.

For example, Outbreak Alert notes that *Campylobacteriosis* is a common GI illness and that it virtually never occurs in an outbreak situation. Because it is not associated with outbreaks CSPI's report ignores *Campylobacter's* role in foodborne illness. There is no consideration of this pathogen in any of CSPI's data.

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illnesses caused by products regulated by the FDA, a result that USDA officials find comforting. While *Outbreak Alert* makes a major contribution to the literature on risks from specific foods, its design limits it value in assessing the overall burden of foodborne illness and the relative number of people who get sick as a result of consuming FDA regulated versus FSIS regulated foods. By reporting only illnesses associated with outbreaks and leaving out illnesses caused by *campylobacter*, the most common cause of bacterial foodborne illness and a pathogen most often associated with poultry, the CSPI studies reduce enormously the number of illnesses associated with FSIS regulated foods and emphasize illnesses caused by FDA regulated foods. *Campylobacter* is the only pathogen excluded from the CSPI study. The categories of foods used in the CSPI study further shift the foodborne illness burden to FDA. *Outbreak Alert* combines all fruits and vegetables into one category—"produce"—and divides meat products into 2 categories "red meat" and "poultry." As a result, the CSPI studies report that FDA regulated foods cause more illnesses than FSIS regulated foods. However, when "meat" is consolidated in a manner similar to "produce," the number of outbreak related illnesses associated with USDA regulated foods is greater than the outbreak related illnesses associated with FDA regulated foods, even though it continues to exclude the millions of illnesses caused by *campylobacter.*

The FSIS expert elicitation presents the same problem. The FSIS, directed participants in the panel to ignore illnesses caused by *Campylobacter.* This appears to be because THE FSIS wanted to be able to state that a study produced by a respected consumer organization came to the same conclusion that its own expert panel did.

There are other problems with the FSIS elicitation. The Agency has stoutly defended its use of expert opinion rather than case studies or food specific risk assessments to attribute illnesses to the foods it regulates. These expert elicitations are the basis for allocating inspection resources in both processing and poultry slaughter.

The Agency ignores the fact that even those who endorse the occasional use of expert elicitations note that it is the least reliable of the methods to attribute risk. Resources for the Future which conducted another expert elicitation states that expert panels are not the best way to gather data but can be useful, in the absence of other data. RFF suggests that the best way to overcome the inherent weaknesses of this process is to choose a panel that is both large and diverse. The RFF expert panel had 45 members. The RFF panel included a number of medical and public health experts. In addition to public health experts from state and local health departments, RFF included representatives from medical schools. The FSIS panel had 17 members. The members were heavily weighted toward individuals whose background was the food industry and schools of agriculture. All of the public health representatives were from government agencies. The FSIS panel's results were limited by the restricted breadth of its membership.

The FSIS seeks to give credence to its own expert elicitation by citing similarities to the results from CSPI and RFF. However, the author of the RFF study presented a memorandum to the FSIS saying the Agency had not reported accurately on the RFF data and taking exception to the averaging of data across the FSIS, CSPI and RFF studies.

In fact a close look shows that the RFF results are not similar to those of the FSIS and CSPI with regard to the risk from poultry products. CSPI and the FSIS data do not include the risk from *Campylobacter* related illnesses and RFF data do. If you subtract the risk of foods created by *Campylobacter* from the RFF results they would no longer agree with the the FSIS and CSPI data.

CFA believes the FSIS must provide the public with a very specific timeline for the implementation of its new programs. We urge that the timeline be realistic about the very substantial problems that must be addressed before proposed rules, final rules or implementation is attempted.
At the NACMPI meeting, the Agency staff distributed a timeline for carrying out the program for processing and slaughter inspection. The timeline anticipated the staff submitting plans to the Department, OMB and others reviewing a proposed rule change to implement its new inspection program by summer 2008. The staff intended to submit the proposed rule for poultry slaughter to the Agency administrator and OIG in March 2008, to OGC next month, to OMB "this spring" and to publish the proposed rule during the summer. This timeline means they are rejecting any recommendation to acquire additional data and suggests the Agency has no intention of paying any attention to any comments received by stakeholders.

Most important, the FSIS staff acknowledges that the new information technology system that is essential to implementing the program will not be in place until summer 2009. The FSIS has never yet met a deadline for implementing any IT program and OIG has been exceptionally critical of the Agency's inability to construct an adequate system but the Agency is assuming now that everything will work on time and pushing to put out a rule before it knows if the system works.

The NACMPI adopted a resolution referencing this continuing inadequacy in the Agency's information technology and data gathering program and noting the need to have the information system in place before the implementation of other elements of the proposal.

CFA and other consumer groups have requested an updated timeline but have not received one.