
From: Patricia Lovera [plovera@fwwatch.org]
Sent: Wednesday, August 30, 2006 11:03 AM
To: FSIS RegulationsComments
Subject: Docket # FSIS 2006-0017
Attachments: TSC comment final .doc; ATT1508421.htm

Please find pasted below and attached our comment regarding Docket # FSIS 2006 -0017.

August 30, 2006

Program Evaluation and Improvement Staff

Food Safety and Inspection Service

U.S. Department of Agriculture

Room 3833 South Building

1400 Independence Avenue SW

Washington, DC 20250-3700.

RE: Docket No. FSIS-2006-0017

Dear Sir or Madam:

On behalf of the non-profit consumer organization Food & Water Watch (FWW), I welcome this opportunity to comment on the organization, operations, and services provided by the Technical Service Center (TSC).

FSIS stated goal in establishing the TSC, that of creating a central resource to provide comprehensive and consistent technical advice quickly for the agency's new HACCP inspection program, was a prudent and admirable one. Consistent interpretation of regulations is necessary in garnering and maintaining respect for any regulatory program, both within the regulated industry and among an agency's frontline employees. It is also essential in enabling frontline personnel to enforce the new regulations correctly. Further, consistent application of new regulations is essential in enabling agency policymakers to determine, over time, which of the new policies are effective and which are not. The agency's core mission of consumer safety is jeopardized when the agency cannot determine whether or how often the established regulations are being followed in a consistent manner.

Therefore, FWW believes that this initiative, to improve the TSC to foster consistent application of the regulations, is a necessary and very important effort. We offer the following observations in the hope that the agency will take the appropriate steps to modify TSC's role, policies and procedures so that it provides the type of service for which it was originally designed. Because the agency presents the TSC as the hub of regulatory enforcement, we also offer comments about other instances of inconsistent application of the regulations, assuming that changes at the TSC will necessitate improvements across the agency. We are aware that the agency has recently begun the process of implementing new initiatives, such as the website Q&As, to improve the functioning of the TSC. We are not confident, however, that the agency has exhibited the necessary commitment because certain core problems remain.

1. Inconsistencies

Because the HACCP program involved new regulations, new requirements for industry, and new tasks for inspectors, the agency was well advised to establish the TSC as an accessible resource to field the inevitable questions that would arise during implementation. Unfortunately, it seems that the agency is unclear about the new policies, resulting in contradictory interpretations of the regulations amongst FSIS officials, causing numerous problems and diminishing the value of the services that the TSC initially provided.

9/5/2006

From June through November of 1999, I collected 451 responses to a survey I designed to learn about federal inspectors experience with implementation of the new HACCP system. These responses revealed that more than half of the responding inspectors felt that they were impeded in enforcing the law because of conflicts over the regulations; in fact, more felt that conflicts *between government officials*^[1] were a problem than those who felt conflicts *between government and industry officials*^[2] were a problem.

With respect to the TSC, approximately one third of respondents^[3] to the survey were aware of instances when the TSC issued contradictory responses. Only 17% of respondents^[4] reported that TSC resolutions were consistent with their training all of the time. One inspector complained that:

The Tech Center gives out so much contradictory and useless information that I will not call them unless I absolutely have to... They have a reputation for not being accountable for their wrong answers. This leaves an inspector feeling that he is on shaky ground and that there are no rules anymore.^[5]

Since then, inconsistent applications of the regulations, some directly involving the TSC, have been noted by reviewing agencies. For example, the USDAs Office of Inspector General (OIG) noted that some agency officials believed that the agency's policy was to sample a supplier's product when *E. coli* O157:H7 contamination was found at a grinding facility and there was only one supplier of raw materials, whereas TSC staff apparently believed that it was the agency's policy that suppliers' products would *not* be sampled in that situation.^[6]

Also, both the OIG^[7] and the Government Accountability Office^[8] have discussed the agency's failure to establish a clear policy on how many repetitive violations of the same kind warrant stronger enforcement action. Perhaps this problem originates with policy makers, not with the TSC, but the agency's efforts to standardize the interpretations of agency regulations may be largely meaningless if clear policies are not established for foundational concepts.

Unfortunately, we continue to receive reports, from inspectors and members of the regulated industry, of inconsistent answers from different staff members of the TSC and/or of continuing discrepancies in interpretation of the regulations between the TSC and other agency officials. For example, I recently spoke with a small plant owner who told me that in the past two years he has had to acquiesce to the different interpretations of the regulations from the Inspector In Charge (IIC) who regularly inspects his plant, the IIC's Circuit Supervisor, visiting FSIS veterinarians, and two different Enforcement, Investigation and Analysis Officers (EIAOs).

While the original inconsistencies could be attributed to initial kinks that needed to be worked out of the system, problems that remain at the TSC, and the inconsistencies that persist in the Agency's enforcement of the regulations, must have a different source. One of the touted strengths of HACCP was its flexibility, but the owner mentioned above and many others tasked with complying with or enforcing the regulations are now suffering from flexibility fatigue due to the lack of clearly identifiable rules and concepts.

Although it is not clear from the referenced Federal Register Notice or other agency documents, we would assume that the agency has established one office, presumably the TSC, as the single source for interpretation of the regulations. We would like to believe that all frontline personnel responsible for regulatory enforcement, including inspectors, veterinarians, Circuit Supervisors, District Managers, compliance officers, EIAOs and any others, are instructed to consult with the TSC when questions arise, but wonder if this common sense arrangement is the standard protocol. For example, the agency directive for EIAOs makes no mention of contacting the TSC with questions.^[9] If the agency wants to foster consistent applications of FSIS regulations, rules, and policies, it must establish a single conduit for their authoritative interpretation.

The agency published an update on the TSC in November 2005 for presentation to the National Advisory Committee on Meat and Poultry Inspection.^[10] It presented a number of actions that the agency was taking to improve the TSC. For example, it said the TSC will include headquarters policy staff in weekly meetings. Further, it said the TSC is meeting quarterly with Office of Field Operations headquarters on technical issues. These actions are only vaguely described but, as articulated, do not seem to be vigorous enough. If the TSC is to be a solid bridge between policy makers and the field, it seems that more interdependent communications should be routinely taking place.

There may be some inconsistencies that do not have their source in organizational or procedural inadequacies. In order to identify and be able to address these situations, we believe that the agency needs to focus on areas subject to the most frequent inconsistent interpretations and rigorously assess whether the relevant rule needs to be more clearly expressed, whether FSIS staff need to be better trained regarding the rule, or whether the rule needs to be scrapped and replaced by something more administrable.

2. Reluctance to Provide Answers

One of the disturbing, concomitant symptoms of the chronic malaise in the system that causes the inconsistencies has been reluctance, or perceived reluctance, of TSC staffers to want to be accountable for their answers to inspectors' questions. Early on, there was a reluctance to issue answers in writing. Recently, inspectors have been able to get written answers to written questions but, too often, it may take two days. This is inadequate. Inspectors on the frontline very often need prompt answers because the safety of food that will enter commerce and/or the economic well being of an establishment are at stake. As one inspector said, It's like calling up a suicide hotline and being told that someone will get back to you once they've studied the manual. Again, if it is so difficult for even the TSC experts to

determine the correct course of action in a particular situation, we have to wonder whether some of the regulations, policies and rules might be too vague to be practical.

The reluctance to put the rules in writing seems to extend beyond the Tech Center. For example, the OIG mentioned in its ConAgra report that the policy for sampling suppliers products after an *E. coli O157:H7* positive was unwritten.^[11] We cannot fathom why such a seemingly critical policy would be unwritten unless it was a policy that FSIS wanted to claim that it had, but did not want employees to actually follow. FSIS needs to identify areas where policies are not only vague, but are not written down. The agency is too large of bureaucracy to be able to function effectively with rules that are not clearly established.

For some period of time (we are not aware of the inclusive dates), including in 2005, the TSC would provide written answers to questions, at the end of which was included the following boilerplate disclaimer:

"The above correspondence is technical information based upon published USDA documents. It is not direction and should not be followed as such. Program employees having questions regarding direction or actions to be taken based upon the information provided in this email message should contact their immediate supervisor for guidance."

Dr. Masters recently informed a group of consumers that this disclaimer on written answers from the TSC has been discontinued, however the same spirit persists in another form as will be discussed below.

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- Inspectors frequently feel vulnerable and unsupported by their agency;
- At times, inspectors are left unprotected from unfavorable supervisory evaluations;
- It creates the impression that agency officials are not confident about their interpretations of the regulations, unfortunately bolstering some inspectors sentiments that HACCP stands for Hardly Anyone Comprehends Current Policy;
- It creates unnecessary animosity in industry personnel who are being given contradictory instructions and opinions from regulators;
- It opens inspectors up to harassment by industry employees and managers;
- It creates the impression that perhaps the agency or agency officials believe they benefit more by maintaining this regulatory flexibility than they would if clear rules were published.

3. A Question of Training

According to agency publications, including the Federal Register Notice seeking comments on the TSC, the TSC is involved with training. For a number of years, we've been hearing from inspectors who have taken the Food Safety Regulatory Essentials (FSRE) training. While many have said that they appreciated the FSRE training because it provided them with a new understanding of their enforcement authorities, most have mentioned a disturbing response to an oft-asked question. In the Q&As, inspectors often pose the following problematic scenario:

My supervisor has instructed me to do things other than what I have just learned in this training. What should I do when I go back to my duty station should I follow this training or follow my supervisor?

Invariably they are told to follow their supervisor. Inspectors report feeling demoralized by this instruction because again they cannot rely on a standard policy established by FSIS officials, and instead must attempt to do their jobs in an idiosyncratic environment

with little hope that clear rules will be established.

Training cannot be treated as perfunctory exercise and a formality. The agency must commit to the concepts it teaches and any contradictory instructions issued by supervisors must be identified and reviewed. Also, it is unclear from FSIS documents whether the TSC originates or coordinates all of the training for inspectors, veterinarians, Circuit Supervisors, EIAOs, compliance officers, District Managers, any other FSIS personnel who must enforce the regulations, and new TSC staff members themselves. If not, they should be responsible for creating or at least signing off on the training materials and learning experiences for all.

4. The TSC as a Progressive Resource

In November 2005, the agency presented the National Advisory Committee on Meat and Poultry Inspection (NCAMPI) with the then-current initiatives being undertaken by the TSC to improv[e] its function and service.^[12] The first focus identified was [d]eveloping and disseminating additional Q&As and related materials on FSIS technical issues [including] generating new Q&As, based on a review of telephone and email questions coming into the TSC, and posting them to a Q&A page on the FSIS web site.^[13] We believe this is a very worthwhile project.

As of August 28, 2006, however, the agency's website on Q&As^[14] lists only 7 FSIS Notices, presumably the codification of answers to questions received by the agency. The Agency's update to the NCAMPI did not mention that the Q&As presented would be limited to those of most interest to industry but the website page is called Business and Industry: Technical Service Center Questions and Answers. Additionally, all appear to be quite specific (e.g. Verification of Establishment's Reassessment of HACCP Plans to Address Mechanically Tenderized Beef and Verification Activities at Establishments that Transport or Receive Cattle Carcasses or Parts with Vertebral Columns that Contain Specified Risk Materials) and on a very limited number of topics. Therefore, as a collection they certainly do not begin to address the range of issues which must have been presented over the years by inspectors. If TSC responsive publications are to provide any meaningful assistance, there must be more than this token offering.

We believe that the TSC must implement a very robust program to unify FSIS employees enforcement of the regulations. The NCAMPI Update mentions getting feedback from the field on the TSCs performance. We support this idea and hope that the agency is already well into this project. We also believe that the agency should begin a period of reevaluation and develop mechanisms to record and analyze all conflicts over agency policy. For example, when one EIAO decides that a HACCP plan, which had been approved by the previous EIAO, is inadequate, TSC analysts should determine the cause of the differing assessments. Or, when an inspector believes that the FSRE training would mandate one action, and her supervisor believes that a different action is called for, a record of the issue should be sent to the TSC. In some cases, one person (whether FSIS employee or industry member), will be right, but the TSC can credit these conflicts and their participants as part of an important, systematic, process of regulatory correlation. The Agency should then identify and prioritize the rules, policies and issues generating the most extreme differing interpretations and those generating the greatest number of differing interpretations and should begin to systematically address these problem areas, either by clarifying the rule or policy and how it should be enforced, and then disseminating this information to all field personnel and members of the regulated industry, or determining that the rule or policy is not administrable as conceived, and developing a replacement for it. Should you have any questions regarding these comments, please feel free to contact me at (201) 330-1618.

Sincerely,
Felicia Nestor
Senior Policy Analyst

[1] 197 of 338 responding inspectors (58%). The Jungle 2000. Felicia Nestor and Wenonah Hauter. Public Citizen. 2000. Pg 62.

<http://www.foodandwaterwatch.org/food/the-jungle/?searchterm=The%20jungle>

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[6] Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant. USDA Office of Inspection General. Report No. 24601-2-KC. September 2003. Pg. 45-46.

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[8] MEAT AND POULTRY: Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses. GAO-02-902. August 2002. Pg. 5.

[9] <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5100.1.pdf>

[10] http://www.fsis.usda.gov/OPPDE/NACMPI/Nov2005/NACMPI_Update_on_TSC.pdf

[11] Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant. USDA Office of Inspection General. Report No. 24601-2-KC. September 2003. Pg 45.

[12] National Advisory Committee on Meat and Poultry Inspection, Update on the Technical Service Center.

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[13] Ibid.

[14] http://www.fsis.usda.gov/HELP/FAQs_TSC/index.asp



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In November 2005, the agency presented the National Advisory Committee on Meat and Poultry Inspection (NCAMPI) with the then-current initiatives being undertaken by the TSC to “improv[e] its function and service.”¹² The first focus identified was “[d]eveloping and disseminating additional Q&A’s and related materials on FSIS technical issues [including] generating new Q&As, based on a review of telephone and email questions coming into the TSC, and posting them to a Q&A page on the FSIS web site.”¹³ We believe this is a very worthwhile project.

As of August 28, 2006, however, the agency’s website on Q&As¹⁴ lists only 7 FSIS Notices, presumably the codification of answers to questions received by the agency. The Agency’s update to the NACMPI did not mention that the Q&As presented would be limited to those of most interest to industry but the website page is called “Business and Industry: Technical Service Center Questions and Answers.” Additionally, all appear to be quite specific (e.g. “Verification of Establishment’s Reassessment of HACCP Plans to Address Mechanically Tenderized Beef” and “Verification Activities at Establishments that Transport or Receive Cattle Carcasses or Parts with Vertebral Columns that Contain Specified Risk Materials”) and on a very limited number of topics. Therefore, as a collection they certainly do not begin to address the range of issues which must have been presented over the years by inspectors. If TSC responsive publications are to provide any meaningful assistance, there must be more than this token offering.

We believe that the TSC must implement a very robust program to unify FSIS employees’ enforcement of the regulations. The NACMPI Update mentions getting feedback from the field on the TSC’s performance. We support this idea and hope that the agency is already well into this project. We also believe that the agency should begin a period of reevaluation and develop mechanisms to record and analyze all conflicts over agency policy. For example, when one EIAO decides that a HACCP plan, which had been approved by the previous EIAO, is inadequate, TSC analysts should determine the cause of the differing assessments. Or, when an inspector believes that the FSRE training would mandate one action, and her supervisor believes that a different action is called for, a record of the issue should be sent to the TSC. In some cases, one person (whether FSIS employee or industry member), will be right, but the TSC can credit these conflicts and their participants as part of an important, systematic, process of regulatory correlation.

The Agency should then identify and prioritize the rules, policies and issues generating the most extreme differing interpretations and those generating the greatest number of differing interpretations and should begin to systematically address these problem areas, either by clarifying the rule or policy and how it should be enforced, and then disseminating this information to all field personnel and members of the regulated industry, or determining that the rule or policy is not administrable as conceived, and developing a replacement for it.

¹² National Advisory Committee on Meat and Poultry Inspection, Update on the Technical Service Center. http://www.fsis.usda.gov/OPPDE/NACMPI/Nov2005/NACMPI_Update_on_TSC.pdf

¹³ Ibid.

¹⁴ http://www.fsis.usda.gov/HELP/FAQs_TSC/index.asp

Should you have any questions regarding these comments, please feel free to contact me at (201) 330-1618.

Sincerely,

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