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S.T.O.P. -- Safe Tables Our Priority
P.O. Box 46522 Chicago, IL 60646 Website: www.STOP-USA.org
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June 3, 1999

97-068N
97-068N-81
Nancy Donley
Heather Klinkhamer

Mr. Thomas Billy
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
Jamie Whitten Building
14th and Independence Avenue, SW
Room 331-E
Washington, DC 20250

Dear Administrator Billy:

The Food Safety and Inspection Service (FSIS) is responsible for several significant improvements to our nation's food safety policies. Its primary achievements include declaring the deadly and virulent E. coli O157:H7 (O157) an adulterant in ground beef, initiating the O157 random sampling program and significantly revising the meat and poultry inspection regulations, including the establishment of performance standards coupled with microbial sampling. The revised regulations and O157 policies were issued shortly after a devastating O157 outbreak in 1993 caused over 700 illnesses and at least four deaths.

O157 is a very dangerous pathogen: one ounce of it is enough to kill everyone in the upper midwest of this country.[1] The Centers for Disease Control and Prevention (CDC) estimate that up to 41,000 Americans suffer and 244 die from O157 infection each year.[2] According to data collected by the CDC between 1982 and 1996, nearly a third of O157 outbreaks have been linked to ground beef.[3]

Since FSIS' O157 random sampling program began in 1994, it has detected O157 and initiated removal of potentially deadly ground beef from the market place on 31 occasions. The number of positive tests have risen sharply to 14 in FY 1998 and to eight so far in FY 1999. Detection and removal of deadly product from commerce has very likely prevented numerous illnesses and deaths. S.T.O.P. -- Safe Tables Our Priority (S.T.O.P.) strongly supports this program.

As an organization composed largely of O157 victims and as the entity that brought the adulteration loophole to the Agency's attention in May 1998, S.T.O.P. was very surprised and deeply disturbed to learn that FSIS had retreated from implementing an

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[1] Manning, Anita, "Deadly Strain of Food Poisoning is Hard to Detect, Difficult to Track." *USA Today*, May 13, 1997. p. 2A.
[2] Meeting with Dr. Fred Angulo, Dr. Patricia Griffin, Dr. Paul Mead and Dr. Robert Tauxe of CDC November 19, 1999.
[3] Dr. Fred Angulo, presentation at the USDA's Technical Meeting to Solicit Input for a Survey on Browning in Hamburger in Washington, DC on August 20, 1997.

important consumer protection policy with serious repercussions for public health and safety. On May 14, 1999 FSIS extended suspension of the O157 definition clarification until June 15 at the earliest.

S.T.O.P. is concerned not only that the Agency has demonstrated at best weak will and at worst disregard for public health in failing to rectify the adulteration definition, but that FSIS has handled the reevaluation of its O157 policies in a questionable manner. There are at least two issues before the Agency: the definition of adulteration with regard to O157 and the O157 random sampling program directive. Grinding of O157- tainted raw materials will result in O157-tainted ground product. This fact has little bearing on the current O157 random sampling program, but it has significant relevance to the adulteration definition. **At the very least the government should immediately attempt to prevent intentional use of O157-raw materials in non-intact products by implementing and enforcing the clarification policy.**

On January 15, 1999 FSIS announced to industry and consumer groups that the definition of O157 adulteration was being clarified to address raw materials for use in non-intact product. The clarification policy was published in the *Federal Register* on January 19, 1999. In both the notice and in the policy backgrounder issued in January 1999 FSIS asserted that the clarification policy was at least partially based on deliberations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

The January 19 notice encouraged the public to comment on the Agency"s "policy regarding beef products contaminated with Escherichia coli O157:H7 and to afford the public an opportunity to submit comments and recommendations relevant to the Agency's policy, and any regulatory requirements that may be appropriate to prevent the distribution of beef products adulterated with this pathogen." On January 15, we were told that the clarification was in effect. But by January 19 FSIS decided not to act upon the new clarification until the comment period for the notice closed on March 22.

On March 8, FSIS held a public meeting on its O157 policies in which two S.T.O.P. representatives participated. This meeting was basically a forum for an industry coalition, coordinated by the American Meat Institute (AMI), to propose a vague O157 carcass study. The intent of these presentations was questionable. Although they had over a month to prepare for the meeting, the presenters hadn't yet committed the proposed plan to paper. The presenters could not respond to questions about major details of the research proposal, but they clearly articulated the changes in O157 policies that they wanted as a result of the study. The purpose of the study proposal appeared to be delay of the clarification policy and relaxation of the O157 random sampling program standards.

S.T.O.P. supports food safety research, and the organization will submit comments on the study. However, we are concerned that such a flimsy study proposal succeeded in quickly shifting the Agency's attention from consumer protection to food industry interests. Discussion about the proposed study diverted FSIS from "policy and regulatory changes to ensure that consumers are protected against meat products adulterated with E. coli O157," to discussion about additional criteria plants could meet to avoid testing under the FSIS random sampling program for O157 in ground beef. The study has no relation to the adulteration definition or to the premise that grinding O157-contaminated raw materials will result in O157-contaminated ground beef.

The type of study that AMI proposed is the type of research that S.T.O.P. expects from an industry that repeatedly states its top concern is food safety. But we are concerned about the motivation for this study. The purpose of the study should be improving food

safety rather than scoring exemptions from the O157 random sampling program and delaying the implementation of the adulteration clarification.

It wasn't until April 5, well past the March 22 comment deadline, that a written study protocol was submitted to FSIS. No copy of the plan was sent to the Docket clerk. Instead, it was directed to the FSIS Administrator. Because the study was not submitted to the Docket, it was not available for public review without submitting a FOIA request.

On April 21, FSIS and AMI met to discuss the study protocol. This was a closed meeting between the trade association and the Agency. Although the study was used to re-open the comment period on the clarification policy, the public was not invited to participate in this meeting.

The study protocol was not submitted to the Docket, but AMI and FSIS clearly considered the study relevant to the Docket. On May 14, FSIS announced that the AMI study protocol would be published in the *Federal Register* for public comment. The announcement noted that the Docket for the clarification policy was to be re-opened. However, FSIS didn't notify the public that the clarified adulteration definition was suspended until the June 15 comment deadline.

While S.T.O.P. appreciates the opportunity to comment on the study, we find it strange that FSIS is publishing the protocol for a study to be conducted by a non-government entity in the *Federal Register* for comment. It is our understanding that the study is not funded in whole or in part by the government. Further, we are not sure what bearing our comments will have upon the study or the Agency's evaluation of it. To our knowledge, AMI has not promised to incorporate public comments into its study.

Furthermore, it appears that the comments submitted will be immaterial because the Agency told AMI to move forward with the study before receiving or reviewing study comments. In a letter to AMI dated May 13, you wrote "industry should proceed with the pilot test rather than wait for the Agency's review of any comments in response to the protocol." We do not understand why the O157 adulteration loophole was extended to the June 15 comment deadline, especially when the Agency told AMI to move forward with the study.

Both AMI and FSIS appear wedded to study results before the research has begun. Kim Rice of AMI wrote to you that the industry coalition agreed to submit to FSIS "test protocol that would provide FSIS with information to support the coalition's recommendations for changes to Directive 10,010.1." She states that the protocol for a single, four week study "will enable FSIS and the industry to establish a system to verify routinely slaughter plant interventions used to control E. coli O157:H7 contamination on carcasses and to define reliable means for reducing the risk of E. coli O157:H7 in beef." In the response to AMI, you wrote, "FSIS agrees that the increased carcass testing performed according to the protocol and control of contaminated product should result in greater food safety." The remainder of the FSIS letter includes detailed projections of policies to be implemented should the study bear the type of data both parties anticipate. S.T.O.P. is concerned that a study conceived and planned in such a charged context can be carried out in an unbiased, scientifically supportable manner.

In its letter to AMI, FSIS provides a list of study results needed to alter the random sampling program policies as AMI has requested. Based on the content of this letter, it appears that FSIS is prepared to dramatically revise one of the most important public health programs at the Agency based on the results of a single, four week study. It appears that the Agency has little concern about the obvious biases of the entities conducting the study.

Further, FSIS seems ready to significantly change an important public policy without scientific consensus.

Since S.T.O.P.'s inception the Agency has accrued a formidable food safety record. S.T.O.P. was delighted when FSIS announced the O157 adulteration definition clarification. We considered it a significant step towards the Agency's consumer protection and safety goals. We proudly stated this in our most recent newsletter, but now we are deeply concerned about the Agency's recent actions. Our O157 victim members are simply outraged by the Agency's decision to suspend the clarification policy.

S.T.O.P. strongly urges the Agency to review and rectify its evaluation of O157 policies. First, FSIS should immediately implement the clarified adulteration definition. Second, FSIS should reconsider the implications of the AMI study in the context of scientific consensus and unbiased research. Third, we recommend that FSIS develop a clear policy for handling counter proposals in response to its own proposals. Counter proposals officially recognized by the government should be subject to the same policies and timelines guiding federal proposals.

Fourth, we recommend that FSIS implement financial disclosure and conflict of interest policies to aid its evaluation of research and policy advice. The Agency should place greater emphasis on studies that are published in peer reviewed, scientific journals that have conflict of interest policies in place. Conflict of interest policies are standard in human health medical journals such as the New England Journal of Medicine.

FDA, FSIS' fellow federal food safety agency, has implemented financial disclosure rules to inform its evaluation of research. The inspector general of the Department of Health and Human Services said FDA was vulnerable to fraud and abuse without standards in place. Under the FDA policy, researchers must disclose financial interest in study outcomes, including grants or consultant fees. In addition to adopting disclosure and conflict of interest policies to aid review of research grants and study results, S.T.O.P. recommends that USDA advisory committees such as the NACMCF and the National Advisory Committee for Meat and Poultry Inspection adopt these rules.

S.T.O.P. and the Agency have developed a good working relationship to improve food safety policies, and we are confident that the Agency's goal is consumer protection. We appreciate your interest in our concerns and we look forward to your response to the issues raised in this letter. We hope that the organization's next newsletter will inform its members that the clarified adulteration definition is in place and enforced.

Sincerely,

Nancy Donley

Nancy Donley
President and mother of Alex Donley (1987-1993)

Heather Klinkhamer
Program Director

Enclosure