BEEF PRODUCT ADULTERATION COMMENTS

March 22, 1999

FSIS Docket Clerk
Docket No. 98-004N
FSIS Docket Room
Cotton Annex
300 12th Street, SW, Room 102
Washington, DC 20250-3700

RE: **Docket No. 97-068N**

Thank you for soliciting comments on the Agency's policy regarding "Beef Products Contaminated with *Escherichia Coli* O157:H7." S.T.O.P. -- Safe Tables Our Priority (S.T.O.P.) is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. Many of S.T.O.P.'s members have been personally impacted or lost loved ones from *E. coli* O157:H7 contaminated ground beef. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness.

In May 1998, S.T.O.P. asked the Agency to address a loophole in the *E. coli* O157:H7 adulteration definition. Currently, *E. coli* O157:H7 is only considered an adulterant if it is found in ground beef. Under this definition, companies could test and find *E. coli* O157:H7 in ground beef raw materials, grind these materials, and sell that raw ground beef to the public without violating the law. Also under the current adulteration definition, companies could lawfully ship to other companies, product that has been tested and found positive for *E. coli* O157:H7, knowing that the receiving company intends to use it in ground beef. S.T.O.P. strongly supports the Agency's effort to prevent the use of *E. coli* O157:H7 contaminated materials in beef products that will be treated in a manner that introduces surface contamination to the interior of the product, such as grinding, flaking, mincing or chopping.

S.T.O.P. applauds the Agency's decision to maintain the announced comment deadline in an effort to expedite implementation of the policy. The swiftest implementation possible will best serve the public's health and safety.

I. *E. coli* O157:H7 and Beef

Nearly a third of the 139 *E. coli* O157:H7 outbreaks reported to the Centers for Disease Control and Prevention (CDC) between 1982 and 1996 were linked to ground beef. This was by far the largest proportion of food product linked to *E. coli* O157:H7 illness. A 1996 Food Net study of 200 sporadic *E. coli* O157:H7 illnesses found that 68% of those made ill ate hamburger five days before illness. Of sporadic *E. coli* O157:H7 cases studied from 1990-1992, 83% of those made ill ate hamburger seven

days before onset of illness. The CDC estimates that hamburger causes 20-30% of *E. coli* O157:H7 outbreaks and 10-20% of sporadic *E. coli* O157:H7 cases [1].

An estimated 94% of Americans consume red meat, and the average American consumes 125.5 pounds each year [2]. Ground beef is one of the most frequently consumed foods in the U.S. Approximately half of the beef consumed in the U.S. is in the form of ground beef [3]. Fast food hamburgers comprised 47% of fast food sales in 1992 [4]. The massive volume of ground beef produced and consumed by the American public, combined with the prevalence of *E. coli* O157:H7 in ground beef and its extremely low infectious dosage, make it imperative that there be strict public health standards and controls of ground beef processing.

II. FSIS' Random Sampling Program

S.T.O.P. strongly supports FSIS' *E. coli* O157:H7 random sampling program at both the processing and retail levels. The program has the effect of encouraging companies to conduct their own voluntary testing and detection of contaminated product, thereby preventing contaminated product from entering the marketplace. By specifying microbial standards to be met, the program also encourages companies to strengthen their own purchasing contract terms.

The random sampling program has been very successful in detecting contaminated product and facilitating swift recalls. S.T.O.P. maintains that it is an integral part of the overall food safety program and that it performs a vital function in protecting the public's health.

1. Product to be Tested

S.T.O.P. encourages FSIS to continue testing raw ground beef products, rather than carcasses and intact products, within the random sampling program. Ground beef is the best product to test for presence of O157 because the pathogen is more likely to be detected in it. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) Meat and Poultry Subcommittee acknowledged that pathogens are likely to be on the surface of intact cuts, and noted that treatments such as tenderizing or injecting may introduce "infectious or toxic organisms" to the interior of the product [5]. An epidemiologist with the Minnesota Department of Health described this phenomenon succinctly in 1993, "It's as if hamburger is all surface by the time you're through [6]." Grinding beef disperses surface pathogens throughout product, thereby making detection more likely.

It is widely acknowledged that the likelihood of contamination or pathogen growth increases as the number of handlers and source materials increases. According to a paper written by members of USDA's Epidemiology and Emergency Response Program, "Methods currently used to produce ground beef make it possible for meat from dozens or even hundreds of cattle to go into any given hamburger patty[7]." It is estimated that one infected animal could contaminate 16 tons of ground beef [8]. Although the presence of *E. coli* O157:H7 may be very low in individual animals, its presence in the food supply is amplified through production practices that mix contaminated with uncontaminated product, thereby spreading the organism.

An article authored by USDA staff offers an example of the way in which contaminated ingredients spread through ground beef processing. "To produce ground beef, large commercial meat packers may purchase raw meat from several different sources, both domestic and foreign. ...several lots were produced each day. Into each of these lots, which ranged in size from 2 tons (1.8 metric tons) to almost 30 tons (27.2 metric tons), went boneless boxed beef from two to 11 different sources located in two to four different states. Some of these sources were purveyors, who had in turn purchased carcasses from several different slaughterhouses [9]." Meat included in the lot of Jack in the Box hamburgers that caused over 700 illnesses was traced to three suppliers who had received meat from Canada, New Zealand, and the U.S. Trace back to one of these three suppliers led to five slaughter houses and 443 individual cattle [10]. Product recalled in the Hudson Foods outbreak of 1997 was linked to at least ten potential suppliers [11].

USDA baseline data demonstrates that pathogens are more likely to be detected in ground product rather than carcasses. In tables 1, 2, 4 and 5 (attached) it is clear that the presence of most pathogens and indicator organisms is greater in ground meat and poultry products. Because carcass and ground product tests generated results in colony forming units (CFU) per gram, square centimeter and milliliter, it is sometimes difficult to compare results. Generally, there was a higher number of CFUs in ground product.

USDA baseline data for steers and heifer recovered O157 from 0.2% of carcasses, but testing of cows and bulls did not recover *E. coli* O157:H7 [12]. The raw ground beef baseline survey did not recover *E. coli* O157 from 563 samples collected in 1993 and 1994, but this should not be used to discount the assertion that O157 is more likely to be found in raw ground beef. While the number of carcasses tested for the intact product baseline is known, the number of carcasses pooled to make the ground beef is not known. S.T.O.P. encourages the government to support research on the probability of recovering pathogens and indicator organisms from intact and non-intact meat and poultry products.

The USDA baseline study of ground beef did not recover *E. coli* O157:H7, but other ground beef testing programs conducted around the same time as the baseline study detected *E. coli* O157:H7 with significant frequency. The Agency's random sampling program for raw ground beef recovered one positive per 1,763.7 samples in FY 1995 (see table 3) [13]. In 1993, a fast food company found approximately one *E. coli* O157:H7 positive sample per 200 samples of ground beef [14]. More recent *E. coli* O157:H7 ground beef testing results have detected this pathogen more frequently. In FY 1998, the FSIS random sampling program recovered one positive per 537.8 samples.

There is some indication that the size of the sample tested influences pathogen detection. The larger the sample tested, the greater the probability of detecting *E. coli* O157:H7. The 1993-1994 microbiological survey sample size was 25g compared to the FY 1998 random sample program sample size of 325g [15]. The fast food company tested 50g samples [16].

2. Intermediate Product

Ground beef mixtures can contain up to 10% Advanced Meat Recovery product. In processing or retail establishments other comminuted beef and beef constituents are

added to ground beef mixtures frequently. Intermediate products such as AMR, course ground beef and other ground products added to raw ground beef should be included in the *E. coli* O157:H7 random sampling program.

The fifth positive of FY 1998 was obtained from unopened IBP supplied beef that was to be further ground at Johnson Brothers Wholesale Meats. This offers a valuable example of the need for intermediate product testing. Small meat processors have complained that they often do not have the clout to engage in supplier food safety agreements. Including tests of intermediate product in the program will encourage suppliers to provide higher quality product to grinders and processors who do not have the leverage to require supplier safety specifications.

Supermarkets and restaurants frequently grind additional products into ground meat on hand. An USDA description of a ground beef food chain notes that grocery stores receiving 80 pound packages of course ground beef regrind "along with `table trimmings' (usually fat trimmed from more expensive cuts) and with meat cuts that had been on their shelves for more than 2 days [17]." FSIS estimates that there are approximately 100,000 retailers grinding meat on a regular basis [18]. These retail grinders are processing meat without FSIS processing inspection. Because retailers are frequently increasing contamination risk by regrinding and because these processors are not under continuous inspection, S.T.O.P. supports FSIS' decision to sample a larger proportion of retail ground beef in the random sampling program.

3. Exceptions

S.T.O.P. supports the concept of Directive 10,010.1 of relegating companies that meet certain performance criteria in addressing *E. coli* O157:H7 to a lower priority within its random sampling program. FSIS has established to skip testing of establishments that are aggressively addressing *E. coli* O157:H7. These exceptions from the sampling program ensure that those companies which need to be more aggressively addressing pathogens are targeted by the program. It also meets the goals of a food safety program by providing an incentive for plants to do voluntary testing.

FSIS is currently responding to a FOIA request S.T.O.P. submitted regarding test exemptions. We have not yet received all of the paperwork, but preliminary review of the exempted test forms indicate that the program is not being adequately implemented due to inspector shortages, supplies shortages, misunderstandings about sampling exemptions and poor communication with inspection staff. Once S.T.O.P. receives the complete response to its FOIA request, it will present the document review results to the Agency along with our comments on the program and its implementation.

III. Lot Size

Increased food handling increases the probability of contamination and pathogen growth. If product processed between cleanings contains contamination, other meat or poultry produced between cleanings is likely to be cross contaminated. USDA noted the importance of processing breaks in a 1996 paper, "Complicating the

matter was that all of the lots from any given day had been produced sequentially in the same meat grinder without cleaning the machinery between lots. Such a continuous throughput process makes it impossible to identify the discreet start and ends points of production lots, thereby making it possible for meat or contaminants from one lot to be mixed with those of another [19]." S.T.O.P. supports the current FSIS clean up to clean up identification of lot size.

An examination of the *E. coli* O157:H7 random sampling program supports the current FSIS lot size definition. Plants that yield positive tests are subject to 15 consecutive days of follow up testing. Of the 14 positive results in FY 1998, four positives were detected through follow up testing. Two of these positive follow up tests derived from one plant.

Clearly, cross contamination can persist for a significant period of time. A 1997 study of a *Salmonella* outbreak linked to ground beef demonstrates that cross contamination can persist for several production days. Failure to properly clean one grinder attachment at a butcher shop led to contamination of at least five days worth of ground beef production [20]. A study of poultry evisceration using tracer bacteria on one bird demonstrated that a single tainted carcass cross contaminated the next 42 birds processed and sporadically cross contaminated up to the 150th bird processed [21]. Limiting the lot size to processing between cleanings is more likely to prevent contaminated product from reaching consumers.

Product composed of raw materials from a large number of suppliers is riskier than product composed of raw material from a single supplier. Suppliers pose different risks by virtue of their handling methods. Individual suppliers of raw materials typically produce their product under consistent procedures and treatments. Some may be better than others. Pooling products of "mixed heritage" is likely to yield poorer, riskier product. The larger the pool of raw material added -- the larger the pool of risk variables to be controlled-- the greater the risk and the greater the possibility that the source of contamination will not be identified.

S.T.O.P. recommends that lots or batches be limited to raw material from a single slaughterhouse supplier. This would not only minimize risk by reducing the number of risk variables per lot, but it would also facilitate trace back at least to the slaughterhouse -- where mistakes lead to initial fecal contamination of carcasses.

IV. Mandatory Notification

FSIS should be immediately notified of *E. coli* O157:H7 positive tests in meat products. Independent and in-plant laboratories, slaughter establishments, food processors and retailers should be required to notify FSIS of *E. coli* O157:H7 positive test results in meat. FSIS can then monitor product diversion, market withdrawal, recall and public health alerts to ensure that they are handled in a manner that will best protect public health. FSIS should have authority to review establishment testing records to determine whether product is adulterated and whether record keeping is honest.

The Swedish *Salmonella* control program for meat requires that positive samples be reported to the Swedish Board of Agriculture and National Veterinary Institute [22]. Under the European Communities Zoonoses Regulations (S.I. No. 2 of 1996) laboratories or establishment officials must notify the Minister of Agriculture of positive *Salmonella* results within 24 hours [23].

V. Identification of Intent

In the clarification the Agency defined adulteration of intact product as that which is intended for non-intact use. *E. coli* O157:H7 tainted intact product would not be deemed adulterated unless it was processed into a raw, non-intact product. The decision that an establishment makes about the fate of O157 contaminated intact product would determine whether the product would be processed in a safe manner and sold for a profit or processed in a manner that places consumers at risk and triggers enforcement action by the Agency.

At the March 8, 1999 public meeting, FSIS staff said that product use intent would be established by examining agreements made between suppliers and customers. Usually these contracts describe the intended use of the product. It is unclear to S.T.O.P. when and how the determination of intent will be made in absence of these contracts. Would the definition of adulteration apply to non-intact *E. coli* O157 contaminated product once it is processed into this form or once an establishment declares the fate of the product? Unless the clarification was intended to be enforced retroactively, it appears that notification of positives in intact product would be needed in cases where a supplier or customer agreement did not exist.

The Agency states in "Questions and Answers on Beef Products Contaminated with *E. coli* O157:H7" that marinated beef products are not to be considered adulterated unless the surface is scored. S.T.O.P. recommends that the Agency extend the disposition description to product that is punctured. The organization also urges FSIS to assess whether *E. coli* O157:H7 is absorbed into the product interior along with marinade uptake.

Since 1961, the FSIS established water retention limit for a significant amount of poultry has been 8% of body weight. FSIS has maintained that some water retention in poultry is necessary so that the birds can be cooled quickly in cold water baths. Chicken and turkey pathogenic contamination data indicates that a large proportion of the poultry supply is contaminated with harmful bacteria. Results from the USDA turkey baseline revealed 90.3% were contaminated with *Campylobacter*. Nearly half of the turkeys tested were contaminated with more than one pathogen [24]. A 1998 study by Consumers Union found 74% of fresh, whole retail chickens tested were contaminated with *Salmonella* or *Campylobacter*. S.T.O.P. suspects that the birds have absorbed some of these pathogens along with chill water.

FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables notes that some types of produce soak up pathogens along with wash water [25]. If there isn't any data on pathogen uptake in marinated intact beef, we recommend that the government support this research.

VI. Establishment Responsibilities

The Agency recommends in the "Q and A" document, actions to be taken by establishments when a sample tests positive. S.T.O.P. recommends adding a couple of items to the Agency's list and prioritizing it in a slightly different manner. With our revisions incorporated, the list of establishment recommendations would be: 1/ notify FSIS of the positive test, 2/ review documentation to ensure that procedures are in place for identifying the distribution channels for other beef from the same source materials, 3/ inform other receivers of the same source materials about the positive finding, 4/ conduct rigorous sampling and testing of the source materials if still available, 5/ review the adequacy of its testing protocol, 6/ perform appropriate corrective action before reassessing HACCP plans and 7/ reevaluate the supplier.

Receiving establishments should notify FSIS if trimmings are found positive for E. coli O157:H7. FSIS should improve its recommendation to receiving establishments with same source materials as *E. coli* O157 positive product by eliminating the recommendation to use the product for raw ground beef.

VII. Handling and Disposal

In Sweden, product that tests positive for *Salmonella* is directed to "sanitary slaughter," where slaughter is isolated in separate departments removed from normal slaughter or where slaughter takes place at the end of the production day and under the supervision of the official veterinarian. The slaughter environment must be thoroughly cleaned and disinfected under the official veterinarian's supervision. *Salmonella* positive carcasses are condemned or specially marked as designated for heat treatment [26].

The European Communities Zoonoses Regulations (S.I. No. 2 of 1996) have similar contamination handling requirements. Laboratories or establishment officials must notify the Minister of Agriculture of positive *Salmonella* results within 24 hours [27]. *Salmonella* contaminated eggs or birds are destroyed under the supervision of an official veterinarian or slaughtered in an abattoir or processed in an establishment designated by the Minister. The minister authorizes the disposal or destruction of the eggs or birds. Contaminated eggs are marked, are treated as high-risk material, and are transferred under the supervision of an authorized officer. Contaminated birds are slaughtered under the supervision of an official veterinarian or in a specially designated slaughtering facility [28].

S.T.O.P. strongly recommends that FSIS adopt similar regulations regarding the control and handling of *E. coli* O157:H7 tainted product. *E. coli* O157:H7 positive product should be clearly marked to ensure that it will be handled properly and to avoid accidental release of the product in a form that would cause cross contamination or place consumers at risk. The product should be marked until it is processed in a manner that renders it safe. S.T.O.P. recommends that the contamination markings include an easily identifiable symbol that would make the disposition of the product clear to anyone who sees it. Using a symbol in conjunction

with any other codes or record keeping would increase the chances that even those who are illiterate or unable to read English would recognize that the product deserves special handling.

The movement of *E. coli* O157:H7 product and the intervention treatments used on tainted product should be recorded. Inspectors should be assigned to monitor the flow of this product inside and outside of establishments. The inspector should verify that other products aren't cross contaminated with the *E. coli* O157:H7 positive product by checking processing records and testing contact surfaces exposed to the tainted product. *E. coli* O157:H7 positive product should be monitored until it is processed in a manner that kills the organism and until the records demonstrating that the product has been properly processed are verified.

FSIS may consider requiring plants to seek Agency approval before disposing of product. If the Agency establishes criteria for abattoirs and processors that handle high risk product, such as *E. coli* O157:H7 contaminated product, it may also consider designating establishments that have met this criteria as "sanitary slaughter" or "sanitary processing" facilities and requiring that identified contaminated product be handled only in these facilitates.

FSIS should review the methods that have been used to dispose of *E. coli* O157:H7 contaminated product to determine whether any of these methods pose a threat to public health. CSPI has raised concerns about pathogen contaminated product being disposed in landfills, where it could seep into water supplies. S.T.O.P. includes among its victim members *E. coli* O157:H7 survivors infected by tainted well water. FSIS should approve disposition on a case by case basis or propose a regulation restricting disposal to methods deemed appropriate for public health protection.

VIII. Conclusion

S.T.O.P. whole-heartedly supports FSIS' position "that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product." This policy closes a food safety gap. The results of FSIS' random sampling program demonstrate that *E. coli* O157:H7 contaminated hamburger continues to be prevalent in the marketplace. We commend FSIS for advancing a policy that should substantially improve public protection.

Respectfully submitted,

Heather Klinkhamer
Program Director

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

Table 1. USDA Pathogen Baselines for Beef Carcasses and Ground Beef

	Campylobacter	Salmonella	Listeria	Staphlococcus	Clostridium	E. coli O157:H7
Steers & Heifers	4%	1%	4.1%	4.2%	2.6%	.2%
Cows & Bulls	1.1%	2.7%	11.3%	8.4%	8.3%	0
Ground Beef	.002%	7.5%	11.7%	30%	53.3%	0

Table 2. USDA Microbial Baselines for Beef Carcasses and Ground Beef

	Aerobic Plate Count	APC	Total Coliforms	TC	E. coli Biotype I	E. coli
Steers & Heifers	98.8%	474.7 cfu/cm^2	16.3%	35.3 cfu/cm^2	8.2%	35.3 cfu/cm^2
Cows & Bulls	99.6%	1,130 cfu/cm^2	32.4%	40 cfu/cm^2	15.8%	33 cfu/cm^2
Ground Beef	100%	7,920 cfu/g	92.0%	96 cfu/g	78.6%	54 cfu/g

Table 3. Results of FSIS E. coli O157:H7 Ground Beef Random Sampling Program

	FY 95	FY 96	FY 97	FY 98	Program through FY98
positive test results	3 positives	4 positives	2 positives	14 positives	23 positives

samples tested	5,291	5,326	5,919	7,529	24,065
positives per samples tested	1/1,763.7	1/1,331.5	1/2,959.5	1/537.8	1/1,046.3

Table 4. USDA Pathogen Baselines for Poultry Carcasses and Ground Poultry

	Campylobacter	Salmonella	Listeria	Staphlococcus	Clostridium	E. coli O157:H7
Turkey	90.3%	18.6%	5.9%	66.7%	29.2%	0
Broiler Chicken	88.2%	20.0%	15.0%	64.0%	42.9%	0
Ground Turkey	25.4%	49.9%	30.5%	57.5%	28.1%	0
Ground Chicken	59.8%	44.6%	41.1%	90.0%	50.6%	0

Table 5. USDA Microbial Baselines for Poultry Carcasses and Ground Poultry

	Aerobic Plate Count	APC	Total Coliforms	TC	E. coli Biotype I	E. coli
Turkey	100%	2,090cfu/ml	99.8%	49cfu/ml	98.9%	26cfu/ml
Broiler Chicken	100%	1,912cfu/ml	99.9%	60cfu/ml	99.6%	32cfu/ml
Ground Turkey	100%	14,305 cfu/g	95.5%	156 cfu/g	84.4%	93 cfu/g
Ground Chicken	100%	35,621 cfu/g	99.7%	717 cfu/g	99.3%	286 cfu/g

Data for tables 1-3 come from USDA, FSIS Science and Technology Microbiology Division, "Nationwide Beef Microbiological Baseline Data Collection Programs." between 1992 and 1994. Data for tables 4-5 come from USDA, FSIS Science and Technology Microbiology Division and USDA, FSIS Office of Public Health and Science between 1995 and 1997. For more specific citations, contact S.T.O.P. headquarters.

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14. Telephone conversation with David Theno of Foodmaker August 21, 1997.

15. USDA, FSIS, Science and Technology Microbiology Division, "Nationwide Federal Plant Raw Ground Beef Microbiological Survey: August 1993 - March 1994," April 1996, page 5.

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18. FSIS Directive 10,010.1, Attachment 1, page 5.

19. Gregory L. Armstrong, Jill Hollingsworth, and J. Glenn Morris, "Emerging Foodborne Pathogens: Escherichia coli O157:H7 as a Model of Entry of a New Pathogen into the Food Supply of the Developed World," *Epidemiologic Reviews*, Vol. 18, No. 1, 1996, page 44.

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22. National Veterinary Institute, Swedish Board of Agriculture, National Food Administration, "Swedish Salmonella Control Programmes for Live Animals, Eggs and Meat," 1995-01-16, pages 1 and 14.

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27. European Communities Zoonoses Regulations (S.I. No. 2 of 1996) pages 14[2], 18[2].

28. European Communities Zoonoses Regulations (S.I. No. 2 of 1996) pages 14[2], [2]15.