

**U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE**

Petition for the implementation of a new program)
for microbial testing of raw beef carcasses and)
trimmings for the presence of *E. coli* O157:H7)
_____)

Docket No. _____

**Submitted by the
Center for Science in the Public Interest**

**On Behalf of:
American Public Health Association
Consumer Federation of America
National Consumers League
Safe Tables Our Priority**

July 1,2002

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CITIZEN PETITION

I. Introduction

The Center for Science in the Public Interest (CSPI), with fellow members of the Safe Food Coalition – Safe Tables Our Priority (STOP), American Public Health Association, Consumer Federation of America, and National Consumers League -- hereby petition the Food Safety and Inspection Service (FSIS) to implement a new program, additional to the current testing of raw ground beef, for microbial testing of raw beef carcasses and trimmings for the presence of *Escherichia coli* (*E. coli*) 0 157:H7.

CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter*.

11. Action Requested

E. coli 0157:H7 has emerged as a significant public health concern in the United States over the past decade. Although it is less common than other food-borne pathogens, *E. coli* 0157:H7 has a low infectious dose, is especially virulent, and can cause devastating illness and death, especially in young, elderly, and immune-compromised consumers. In 1994, FSIS declared *E. coli* 0157:H7 an adulterant in chopped and ground beef and began a limited sampling program to test for the pathogen in raw ground beef prepared in federally inspected plants and in retail stores.¹ FSIS established the end-product sampling program for raw ground beef as a means to keep contaminated product from reaching consumers and to spur processors to institute pathogen-reduction programs to reduce the risk of this microbe in beef products.*

Although FSIS has identified *E. coli* 0157:H7 as a food safety hazard reasonably likely to occur in beef production: at present FSIS only tests for the pathogen in raw ground beef from the grinding plant forward into distribution channels. The low infectious dose coupled with the severity of the disease caused by *E. coli* 0157:H7 should compel FSIS to take additional protection measures to guard against this dangerous microbe. While FSIS does require slaughterhouses to test carcasses for *E. coli* biotype I (generic *E. coli*) as a means of verifying that

¹ FSIS Notice 50-94 (Dec. 23, 1994).

² FSIS, Office of Policy, Program Development and Evaluation, National Advisory Committee on Meat and Poultry Inspection, *White Paper on Escherichia coli O157:H7* (Nov. 1999), at p. 1 [hereinafter *White Paper*], available at <http://www.fsis.usda.gov/OPPDE/nacmpi/Nov99/white_paper-11-1.htm>.

³ FSIS, Office of Policy, Program Development and Evaluation, Meat and Poultry Advisory Committee Staff, *Implementing E. coli 0157:H7 Policy in a HACCP Environment*, National Advisory Committee on Meat and Poultry Inspection (May 16-17, 2000), Public Meeting, Issue Paper on Current Thinking, at p. 2, <http://www.fsis.usda.gov/OPPDE/nacmpi/May2000/EColi_Haccp.html>.

their process controls are working to prevent fecal contamination,“ slaughterhouses are not required to test raw beef carcasses and beef trim for *E. coli* O157:H7 – even though intact beef trim is considered adulterated if it contains the pathogen.⁵

In a speech at the Pathogen Reduction conference held May 6-7,2002, Elsa Murano, Undersecretary of Food Safety at the U.S. Department of Agriculture, recognized that, for some families, both microbial testing and the zero-tolerance policy for *Escherichia coli* (*E. coli*) O157:H7 in raw ground beef has “failed miserably” and that “we must do better.” We agree that FSIS must add to its current program.

Based on FSIS’s recognition that *E. coli* O157:H7 is a pathogen likely to be present at all stages of fabrication, particularly slaughter, CSPI and members of the Safe Food Coalition request that FSIS revise its current sampling program at slaughterhouses to incorporate microbiological testing of raw beef carcasses and beef trim for the presence of *E. coli* O157:H7. **Such a program should be in addition to – not a substitute for – the current ground beef testing program.**

We recognize that FSIS is in the process of evaluating public comments and obtaining peer review from the National Academy of Sciences on the draft risk assessment for *E. coli* O157:H7 in ground beef.⁶ However, **FSIS** should not delay taking action while it awaits the outcome of the peer review and risk assessment process. The fact that raw ground beef continues

⁴ **FSIS**, Backgrounder, *Microbiological Testing Program for Meat and Poultry*, pp. 2-3 (June 2000).

⁵ In 1999, **FSIS** recognized that the public health risk presented by raw beef products contaminated with *E. coli* O157:H7 is not limited to raw ground beef products. Therefore, the Agency clarified its policy to state that beef trimmings defined as intact are considered adulterated if they contain *E. coli* O157:H7. Processed products from the contaminated trimmings are considered adulterated and may not be distributed until they are processed to destroy the pathogen. 64 Fed. Reg. **2803** (Jan. 19, 1999).

⁶ 66 Fed. Reg. 55,912 (Nov. 5,2001).

to test positive at many facilities demonstrates that interventions at the slaughterhouse are not totally eliminating the threat of *E. coli* O157:H7. Now that Undersecretary Murano has herself recognized the weakness of the current system, we urge FSIS to proceed without delay. Carcass and trim testing should be adopted and implemented as part of an integrated approach to address this pathogen.⁷

The need to institute microbial testing of carcasses and trim for *E. coli* O157:H7 recently has gained even more urgency. As a result of the Fifth Circuit's decision in *Supreme Beef Processors v. USDA*, FSIS's ability to close down ground beef plants that repeatedly fail government tests showing that they are producing contaminated meat is jeopardized. Therefore, government testing of carcasses and trim before they enter a grinding facility -- where meat from one contaminated carcass can be mixed with and contaminate the whole batch of ground meat -- is a critical addition to increase consumer protection.* It would also provide slaughterhouses with an additional incentive to look for and implement intervention strategies to reduce the levels of *E. coli* O157:H7 on carcasses. Adopting a carcass and trim-testing program would make the *E. coli* O157:H7 program more prevention-oriented and give consumers greater assurance that FSIS is actually catching the hazards in the food supply.

⁷ As part of its farm-to-table approach to food safety, USDA's Plant and Animal Health Inspection Service (APHIS) also should implement a mandatory on-farm HACCP program for *E. coli* O157:H7. One identified intervention strategy to lower the prevalence of this dangerous pathogen in cattle is short-term (i.e. one week) hay feeding before slaughter to reduce *E. coli* shedding. See T.C. Scott, et al., Nebraska Beef Cattle Report 2000, at pp. 39-41; J.E. Keen, et al., Paper at 80th Conference of Research Workers in Animal Diseases (Chicago, Nov. 7-9, 1999). Other pre-slaughter interventions, such as washing cattle prior to entering the slaughterhouse, also would reduce the incidence of *E. coli* O157:H7 contamination among beef cattle.

⁸ Deboned beef trim is used for producing ground beef. After deboning, generally no additional anti-microbial treatments are applied to the material other than refrigeration.

111. FACTUAL BASIS FOR PETITION

A. *E. coli* O157:H7 Is A Significant Public Health Concern

1. *E. coli* O157:H7 Can Cause Serious Illness Or Death, Particularly In Susceptible Sub-Populations.

Common strains of *E. coli* are harmless bacteria that live in the intestines of humans and animals. However, several strains can cause severe illness. *E. coli* O157:H7 is a virulent strain that produces potent toxins (shiga toxins) which adhere to and cause severe damage to the lining of the intestine. Although the infectious dose of the pathogen is uncertain, some experts believe that fewer than 100 organisms can induce an infection.⁹ The Centers for Disease Control and Prevention (CDC) active surveillance network of foodborne illnesses – FoodNet – has reported that there were 631 cases of *E. coli* O157:H7 infections in the year 2000,¹⁰ compared to 510 cases reported in 1999.¹¹ According to the 2000 FoodNet data, 40% of those with culture-confirmed *E. coli* O157 were hospitalized.¹² The highest rate of cases are in children under the age of five.¹³ Preliminary data recently released for 2001 shows that there were 565 laboratory-diagnosed cases of *E. coli* O157:H7 infection.¹⁴ While the incidence of laboratory-diagnosed *E. coli* O157:H7 slightly decreased in 2001, this does not reflect a trend and *E. coli* O157:H7 still remains an

⁹ Stephanie Doores, *Food Safety: Current Status and Future Needs*, a report from American Academy of Microbiology (1999), at pp. 9-10 [hereinafter Doores, *Food Safety: Current Status and Future Needs*].

¹⁰ CDC, *FoodNet Surveillance Report for 2000 (Preliminary Report)*, Sept. 2001, at p. 6, Table 1A [hereinafter *Preliminary FoodNet Surveillance Report for 2000*].

¹¹ CDC, *FoodNet Surveillance Report for 1999 (Final Report)* (Nov. 2000), at p. 7, Table 1A [hereinafter CDC, *1999 FoodNet Surveillance Report*].

¹² *Preliminary FoodNet Surveillance Report for 2000*, at p. 11.

¹³ CDC, *Summary of Notifiable Diseases*, 47 *Morbidity & Mortality Weekly Report* 1-93 (1998).

¹⁴ CDC, *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses – Selected Sites, United States, 2001*, 51 *Morbidity and Mortality Weekly Report* 325-29 (Apr. 19, 2002).

important human pathogen because of the severity and duration of the infection, particularly in children.”

Persons infected with *E. coli* O157:H7 may experience a range of clinical symptoms. Although some infected persons may be asymptomatic, others may experience a range of symptoms, from non-bloody diarrhea to severe bloody diarrhea, other complications, and death.¹⁶ Antibiotics do not improve the illness and some medical researchers believe that medications can actually increase the risk of complications.

In susceptible persons, including children, the elderly and the immuno-compromised, the toxin emitted by *E. coli* O157:H7 can cause an acute form of disease called hemorrhagic colitis, whose symptoms include severe abdominal cramps followed by bloody diarrhea, edema, and erosion or hemorrhage of the mucosal lining of the colon. The illness can be severe enough to cause hospitalization. Infections can lead to a life-threatening complication called hemolytic uremic syndrome (HUS), which is characterized by destruction of red blood cells, acute kidney failure, and neurological complications such as seizure and strokes.¹⁷ Most cases of HUS in the United States are caused by toxic-producing *E. coli*.¹⁸ It is the principal cause of acute kidney failure in children.¹⁹ Persons who develop kidney failure may require prolonged hospitalization

¹⁵ Only about 50% of the FoodNet sites routinely test for *E. coli* O157. *Preliminary FoodNet Surveillance Report for 2000*, at p. 20.

¹⁶ FDA, Center for Food Safety & Applied Nutrition, *Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, “*Escherichia coli* O157:H7,” at p. 1 [hereinafter FDA, *Bad Bug Book*], <<http://www.cfsan.fda.gov/~mow/chap15.html>>; CDC, Division of Bacterial and Mycotic Diseases, Disease Information, *Escherichia coli* O157:H7 (Dec. 2000) [hereinafter CDC, *Escherichia coli* O157:H7], <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm>.

¹⁷ CDC, *Escherichia coli* O157:H7

¹⁸ CDC, *1999 FoodNet Surveillance Report*, at 12.

¹⁹ CDC, *Escherichia coli* O157:H7.

and approximately half of HUS patients require dialysis.²⁰ Between 3-5% of persons with HUS die, resulting in an estimated 61 fatal cases each year.²¹ The elderly are particularly vulnerable to another complication associated with *E. coli* O157:H7 infection -- thrombotic thrombocytopenic purpura (TTP) – a central nervous system disease characterized by seizures and coma -- which can have a mortality rate as high as 50% in the elderly.²²

The 1992-1993 Jack-in-the-Box outbreak in Washington State demonstrates how devastating *E. coli* O157:H7 infections can be. In that outbreak, over 700 cases were reported. One hundred fifty-one patients (31%) were hospitalized, forty-five patients (9%) developed HUS, and four died of complications from HUS. The median age of all case patients was 8-years old.²³

2. *E. coli* O157:H7 Is Prevalent In Cattle

Cattle are considered the primary reservoir of *E. coli* O157:H7 organisms that infect humans, although the bacteria also have been found in sheep, horses, pigs, turkeys, dogs and wild animals, as well as in bodies of water. The pathogen can colonize in the intestinal tract of cattle and be shed in their feces.²⁴ Cattle often are transported to the slaughterhouse under conditions

²⁰ CDC, *Escherichia coli* O157:H7; Robert L. Buchanan and Michael P. Doyle, *Foodborne Disease Significance of Escherichia coli* O157:H7 and Other Enterohemorrhagic *E. coli*, 51 *Food Technology* 69-76 (Oct. 1997), p. 70.

²¹ CDC, *Escherichia coli* O157:H7

²² Doores, *Food Safety: Current Status and Future Needs*, at p. 8. For example, in a 1986 outbreak in Washington State, for example, three seniors developed TTP, two of whom later died. In all, 37 people were sickened in this outbreak.

²³ Beth P. Bell, et al., *A Multistate Outbreak of Escherichia coli* O157:H7-Associated Bloody Diarrhea and Hemolytic Uremic Syndrome From Hamburgers, 272 *Journal of the American Medical Association* 1349-1353 (Nov. 2, 1994)

²⁴ For dairy cattle, *E. coli* O157:H7 shedding has been associated with weaning. Weaned calves were three times more likely to test positive for the organism than pre-weaned calves. See APHIS, Centers for Epidemiology & Animal Health, *Escherichia coli* O157:H7 in U.S. Dairy Calves (Nov. 1994), http://www.aphis.usda.gov/vs/ceah/cahm/Dairy_cattle/ndhep/dhpeco2txt.htm.

that not only increase the likelihood of pathogen transmission from one animal to another but also that make the animals more susceptible to stress-induced reactions, such as increased fecal shedding of organisms.²⁵

E. coli O157:H7 is present at least some of the time on most farms and feedlots. Surveys have reported prevalence rates of *E. coli* O157:H7 in the feces or on hides of dairy and feedlot cattle presented for slaughter ranging from under 1% to over 15%.²⁶ More recent studies, however, have shown an even higher rate of fecal and hide-positive samples. For instance, the USDA's Agricultural Research Service has reported preliminary results of an ongoing survey of fecal samples from feedlot cattle in nine mid-western states showing *E. coli* O157:H7 in up to 75% of samples taken between July and October.²⁷

The prevalence of *E. coli* O157:H7 in cattle appears to depend on the season of the year. Peak periods when cattle shed *E. coli* O157:H7 are during summer and early fall, between July and October.²⁸ Prevalence rates also appear to be influenced by other factors, including the type and age of cattle sampled (whether breeding or feedlot cattle), feed and dietary

²⁵ *Food Safety: Current Status and Future Needs*, at p. 12.

²⁶ Daniel H. Rice, et al., *Escherichia coli* O157 in Cull Dairy Cows on Farm and At Slaughter, 60 *Journal of Food Protection* 1386-1387 (1997) (3.4%); P.A. Chapman, et al., *A 1-Year Study of Escherichia coli* O157 in *Cattle, Sheep, Pigs and Poultry*, 119 *Epidemiology and Infection* 245-50 (1997) (15.7%); APHIS, Centers for Epidemiology & Animal Health, *Escherichia coli* O157:H7 Shedding by Feedlot Cattle (June 19, 1995) (1.8% of feedlot cattle sampled), <http://www.aphis.usda.gov/vs/ceah/cahm/Beef_Feedlot/fdecolitxt.htm>.

²⁷ USDA, *Agricultural Research Magazine*, *E. coli: Unwelcome From Farm to Fork* (Oct. 2000) (hereinafter ARS, *E. coli: Unwelcome From Farm to Fork*). See also Robert O. Elder, et al., *Correlation of enterohemorrhagic Escherichia coli* O157 prevalence in feces, hides and carcasses of beef cattle during processing, 97 *Proceedings of the National Academy of Sciences* 2999-3003 (Mar. 28, 2000) (studying 29 lots of cattle and finding prevalence within lots ranging from 0-100%, with a mean prevalence of 26%; 38% of the lots were hide positive with prevalence ranging from 0-89%) [hereinafter Elder, et al., *Correlation of enterohemorrhagic Escherichia coli* O157].

²⁸ Elder, et al., *Correlation of enterohemorrhagic Escherichia coli* O157; ARS, *E. coli: Unwelcome From Farm to Fork*.

ingredients, and the culture technique used.²⁹

3. Most Human Illnesses Due To *E. coli* O157:H7 Are Foodborne And Associated With Consumption Of Raw Or Undercooked Beef, In Particular Ground Beef

The CDC estimates that food-borne *E. coli* O157:H7 causes approximately 62,458 cases of food-borne illness, 1,843 hospitalizations, and 52 deaths in the United States annually.³⁰ It is likely that the actual incidence of the disease may be underestimated since the organism is difficult to identify if testing is not done during the early stages of infection.

Illness caused by *E. coli* O157:H7 can occur as sporadic cases, clusters, or outbreaks. Outbreaks and clusters of *E. coli* O157:H7 peak during the warmest months of the year, corresponding to the studies showing higher prevalence in cattle during these months.³¹ Outbreaks of *E. coli* O157:H7 are most often associated with the consumption of beef, particularly ground beef, that has not been sufficiently cooked.³² However, other types of foods, including alfalfa sprouts³³ and fresh cheese curds³⁴ have been implicated in some outbreaks. In addition, cross-contamination by infected meat, through improper food handling, with other foods that require no further cooking is also an issue. While most bacteria are killed by the acid

²⁹ Joyce VanDonkersgoed, et al., *The Prevalence of Verotoxins, Escherichia coli O157:H7 and Salmonella in the Feces and Rumen of Cattle at Processing*, 40 Canadian Veterinary Journal 332-38 (May 1999).

³⁰ Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 Emerging Infectious Diseases, 607-625 (Sept.-Oct. 1999), at p. 611 [hereinafter *Food-Related Illness and Death*].

³¹ Elder, et al., *Correlation of enterohemorrhagic Escherichia coli O157*, at p. 7.

³² CDC, 42 *Morbidity & Mortality Weekly Report* 4 (1993).

³³ CDC, 46 *Morbidity and Mortality Weekly Report*, vol. 32, *Outbreaks of Escherichia coli O157:H7 Infection Associated with Eating Alfalfa Sprouts - Michigan and Virginia, June-July 1997* (Aug. 15, 1997).

³⁴ CDC, 49 *Morbidity & Mortality Weekly Report*, vol. 40, *Outbreak of Escherichia coli O157:H7 Infection Associated with Eating Fresh Cheese Curds - Wisconsin, June 1998* (Oct. 13, 2000).

of human stomach juice, *E. coli* can withstand the acid environment of the stomach and thrive.

Since 1999, CSPI has maintained a database of foodborne-illness outbreaks, which includes confirmed outbreaks reported by state-health departments and scientific and medical journals, in addition to outbreaks identified by the CDC.³⁵ The attached table, “*E. coli* O157:H7 Outbreaks 1994-1999,” was summarized from CSPI’s database. There are a total of 96 outbreaks of *E. coli* O157:H7 infection that met CSPI’s outbreak criteria listed in the table.³⁶ CSPI’s data shows that 47% of outbreaks (45/96) and 22% of cases (470/2,105) from *E. coli* O157:H7 were linked to ground beef.

The medical and societal costs of *E. coli* O157:H7 infections are substantial given fatalities among young children and the high cost of chronic conditions such as kidney failure in survivors. USDA’s Economic Research Service estimates that, each year in the United States, foodborne *E. coli* O157:H7 disease costs almost \$660 million to society.³⁷

B. Microbial Testing Of Carcasses And Beef Trimmings Is Necessary To Protect The Public’s Health And To Assure Effective Implementation Of HACCP

1. Continued *E. coli* O157:H7 Positives On Raw Ground Beef Demonstrate That Process Controls At Slaughter Are Not Preventing Carcass Contamination Or Cross-Contamination

In 1994, FSIS initiated its current sampling regime testing raw ground beef for *E. coli* O157:H7 at federally-inspected establishments and retail facilities. There are approximately 1,700

³⁵ These data have been published in CSPI’s *Outbreak Alert!*, updated October 2001, a copy of which is attached. CSPI’s database includes foodborne-illness outbreaks occurring between 1990 and 2001 with a confirmed etiology and food vehicle.

³⁶ See CSPI, *Outbreak-Tracking Methodology*, attached hereto.

³⁷ USDA, Economic Research Service, Briefing Room, *Economics & Foodborne Disease: e. coli* (Updated May 9, 2001), <<http://www.ers.usda.gov/briefing/FoodborneDisease/ecoli/index.htm>>.

establishments producing ground beef under FSIS inspection, and approximately 100,000 retail outlets grind beef on a regular basis.³⁸ Of the ground beef sampled since 1994, almost one-third tested positive in calendar year 2001 alone,³⁹ resulting in 25 voluntary recalls of raw ground and cubed beef for possible contamination with *E. coli* O157:H7.⁴⁰ This year, as of June 13, twenty out of 2,462 samples have tested positive – before the high prevalence season has even begun.⁴¹

The fact that there continue to be a significant number of *E. coli* O157:H7-positives on raw ground beef demonstrates that the zero tolerance policy is not working and that slaughterhouse practices and processes are not entirely preventing contamination of carcasses by fecal material, ingesta, and associated bacteria.⁴² The recent studies showing that *E. coli* O157:H7 is significantly more prevalent than previously thought in the feces and hides of cattle presented for slaughter and that the food-borne illness rate from the pathogen is higher than CDC has previously reported makes it crucial that FSIS act to develop a new testing regime for *E. coli* O157:H7.

FSIS has recognized that “reduction of microbiological contamination in meat and poultry

³⁸ FSIS, Electronic Reading Room: Microbiological Testing Program, *Microbiological Results of Raw Ground Beef Products Analyzed for Escherichia coli O157:H7*, available at <<http://www.fsis.usda.gov/OPHS/ecoltest/index.htm>>.

³⁹ FSIS, Electronic Reading Room: Microbiological Testing Program, *Microbiological Results of Raw Ground Beef Products Analyzed for Escherichia coli O157:H7* [hereinafter *2001 Microbiological Results*], <<http://www.fsis.usda.gov/OPHS/ecoltest/tables.htm>>.

⁴⁰ FSIS, Recall Notification Reports, Active Cases, <<http://www.jiisusda.gov/OA/recalls/rnrfiles>>.

⁴¹ FSIS, Electronic Reading Room: Microbiological Testing Program, *Microbiological Results of Raw Ground Beef Products Analyzed for Escherichia coli O157:H7, Calendar Year 2002* (Updated June 13, 2002), <<http://www.fsis.usda.gov/OPHS/ecoltest/ecpositives.htm>>.

⁴² In 1999, FSIS began using a new method for analyzing samples of products for *E. coli* O157:H7 in raw meat, called immunomagnetic separation (IMS), that is four times more sensitive than previous methods and has increased the probability of detecting low levels of the pathogen. See USDA, News Release, *Glickman Announces Improvement in Testing for E. Coli O157:H7* (Sept. 10, 1999), <<http://www.fsis.usda.gov/OA/news/1999/ectest.htm>>.

is a serious challenge facing USDA and the meat and poultry industry.”⁴³ Testing carcasses and trim for *E. coli* O157:H7 would help meet that challenge and advance the agency’s announced initiative to more fully integrate microbiological testing into its food safety program for meat and poultry.⁴⁴ Carcass testing and trim testing would provide additional safeguards for public health since they would be conducted at a point before grinding when the existence of pathogens can be better corrected. Indeed, the American Meat Institute previously has recognized that testing carcasses “identifies problems farther upstream, thereby helping to limit the possibility of *E. coli* contamination.”⁴⁵

2. Carcass and Trim Testing Would Assist Slaughterhouses and FSIS In Identifying Where Interventions Are Needed And Facilitate Corrective Action

One of the most effective ways of minimizing the risk of carcass contamination by *E. coli* O157:H7 is the adoption by slaughterhouses of critical controls and good manufacturing practices and processes that incorporate the HACCP principles. The presence and amount of bacteria in the end product – ground raw meat -- is primarily influenced by the bacteria on the carcasses, parts, and trimmings. At the slaughterhouse, feces of colonized animals can contaminate not only their own hides and carcasses but workers’ hands and equipment. As carcasses successively pass through the processing line, contamination can spread from one infected carcass to others. Additional carcass

⁴³ FSIS, Backgrounder, *Microbiological Testing Program for Meat and Poultry* (June 2000), hereinafter [*Microbiological Testing Backgrounder*].

⁴⁴ FSIS, *Microbiological Testing Backgrounder*.

⁴⁵ American Meat Institute, *Supplemental Comments Pertaining to Recent Developments Regarding Beef Products Contaminated with Escherichia coli O157:H7*, at p. 3 (Apr. 11, 2000) [hereinafter AMI, *Supplemental Comments*].

contamination can arise from aerosols created during the slaughter and dressing process.⁴⁶

Two studies traced the prevalence of *E. coli* O157:H7 on the hides and feces of live cattle presented for slaughter and then on beef carcasses and trimmings after processing. These studies demonstrate that the frequency of *E. coli* O157:H7 on beef carcasses declines following application of decontamination interventions.⁴⁷ Conducted at 16 slaughter establishments, these studies show that whole-carcass intervention treatments can be very effective in reducing and controlling the risk of *E. coli* O157:H7. Carcass testing by the government would help ensure that all slaughterhouses are employing effective interventions to reduce and eliminate *E. coli* O157:H7 contamination.

While these studies do show that *E. coli* O157:H7 can be reduced during the slaughter process by employing effective intervention strategies, these studies presumably were conducted at establishments using the best intervention strategies and processing techniques. Indeed, the authors of one of the studies noted that their results provide evidence that the plants in the study had prerequisite programs, including good manufacturing practices, Sanitation Standard Operating Procedures (SSOPs), quality control practices, HACCP programs and carcass-decontamination interventions so that carcasses entered the chiller with reduced contamination.⁴⁸

Testing would provide the government with an important new tool to verify the effectiveness of pathogen control systems in beef slaughter plants and other elements of plants' operating systems.

⁴⁶ *Food Safety: Current Status and Future Needs*, at p. 12.

⁴⁷ See, e.g., Elder, et al., *Correlation of enterohemorrhagic Escherichia coli* O157 (finding that significant reductions in the proportion of positive carcass samples were observed between pre- and post-evisceration samples and between post-evisceration and post-processing samples); R.T. Bacon, et al., *Incidence of Escherichia coli* O157:H7 on Hide, Carcass and Beef Trimmings Samples collected From United States Packing Plants, Executive Summary (showing that 0.00% of the carcasses sampled tested positive for *E. coli* O157:H7 after application of decontamination interventions) [hereinafter R.T. Bacon, et al., *Incidence of Escherichia coli* O157:H7].

⁴⁸ R.T. Bacon, et al., *Incidence of Escherichia coli* O157:H7, at p. 3.

Individual plant characteristics, including plant layout and the sanitation, hygiene and manufacturing techniques used during slaughter and processing, have a significant impact on the effectiveness of decontamination measures and on whether meat may become re-contaminated during processing.⁴⁹ Indeed, the USDA's Economic Research Service has found that "differences in plant size, plant procedures, general sanitation practices, worker training, auditing and management competency may account for the wide range of observed contamination of beef carcasses among plants."⁵⁰ Another study has concluded that "[w]ithout the foundation of food plant design, proper sanitation, hygiene and good manufacturing practices, even the best decontamination technologies will fail."⁵¹

Testing beef carcasses and trim for *E. coli* O157:H7 at all federally-inspected slaughterhouses is the best way to assure that effective pathogen-reduction measures, including HACCP control and sanitation SOPs, are implemented at critical control points on an industry-wide basis – not just at the best-controlled facilities – and that corrective actions are taken.⁵² Microbiological testing of carcasses and trimmings for *E. coli* O157:H7 provides verification and continuous feedback to

⁴⁹ As of 1997, there were approximately 812 federally inspected plants slaughtering cattle in the United States. See USDA, Economic Research Service, Technical Bulletin No. 1874, Kenneth H. Mathews, et al. *U.S. Beef Industry: Cattle Cycles, Price Spreads, and Packer Concentration*, at 10 (Apr. 1999), <<http://www.ers.usda.gov/publications/tb1874.pdf>>. However, not every plant employs the most up-to-date processing techniques and intervention strategies for addressing *E. coli* O157:H7. Nor does every plant achieve pathogen reductions during processing similar to those achieved at the plants in the studies.

⁵⁰ Tanya Roberts, et al., *Probabilistic Risk Assessment and Slaughterhouse Practices: Modelling Contamination Process Control in Beef Destined for Hamburger*, published in PROBABILISTIC SAFETY ASSESSMENT PSA '99: RISK-INFORMED PERFORMANCE-BASED REGULATION IN THE NEW MILLENNIUM, Mohammad Modarres, ed., American Nuclear Society: LaGrange Park, Illinois (1999), at p. 810.

⁵¹ John F. Sofos, et al., *Processes to Reduce Contamination with Pathogenic Microorganisms in Meat*, Department of Animal Sciences, Center for Red Meat Safety, Colorado State University (1999), at p 10.

⁵² While changing pre-slaughter feeding practices, such as feeding cattle hay for a period of days prior to slaughter, has been investigated as a strategy for reducing *E. coli* O157:H7 in cattle, studies have shown that the growth performance, carcass characteristics, and grading appeared to be impacted fairly severely. See, e.g., T.L. Stanton & D. Schutz, *Effect of Switching From High Grain to Hay Five Days Prior to Slaughter on Finishing Cattle Performance, 2000* Research Report, Colorado State University, Department of Animal Sciences, <<http://ansci.colostate.edu/ran/beef/tls002.pdf>>.

operators on whether their processes are controlling contamination and potential re-contamination on an ongoing basis. It also assists industry in identifying problems so that effective intervention strategies can be implemented. Indeed, without carcass testing, industry and government cannot evaluate the effectiveness of intervention strategies against *E. coli* O157:H7.

In the preamble to the final HACCP rule, FSIS recognized that “[c]ontinuous efforts are required by industry and government to improve methods for identifying and preventing hazards and to minimize the risk of illness.”⁵³ While government testing of raw ground meat is necessary to assure that final products are not contaminated with *E. coli* O157:H7, pathogen testing further upstream in the production process on raw carcasses and trimmings would be a significant step in verifying that effective processing techniques and intervention technologies are applied at every stage of processing -- **before** a contaminated carcass is ground and contaminates a greater volume of product. The National Advisory Committee on Microbiological Criteria for Foods, in response to questions posed by the FSIS regarding performance standards for ground beef products, has stated that “due to the possibility of bacterial growth between the slaughter and grinding processes, detection of the number of *E. coli* in ground product may not be as direct a measure for the concentration of fecal contamination as on carcasses immediately after slaughter.”⁵⁴

Carcass and trim testing is especially important to address the increasing number of *E. coli* O157:H7 positives being found in raw ground beef. It will help assure that HACCP plans focus on **eliminating** rather than merely **reducing** this pathogen. Eliminating the risk of this pathogen is

⁵³ 61 Fed. Reg. at 38,817.

⁵⁴ NACMCF, *Response to the Questions Posed by FSIS Regarding Performance Standards for Ground Beef Products*, adopted Jan. 25, 2002, Washington, D.C., at p. 8. While the committee was discussing generic *E. coli* as an indicator organism, the same conclusion should be true for *E. coli* O157:H7 as well since the two organisms have similar survival and growth characteristics and a common source.

especially important given its low infectious dose, its virulence and the fact that it targets more vulnerable consumers such as children and the elderly.

3. FSIS Should Not Depend On Consumers To Cook Away The Problem

Despite the use of various intervention strategies during processing of beef post-slaughter, a proportion of ground beef servings each year are contaminated with *E. coli* O 157:H7. If the meat is not found and recalled, consumers are left with the responsibility for ensuring its safety by assuring that the meat is cooked to a temperature high enough to kill all the pathogen.

Although researchers have shown that color and texture are not reliable indicators of doneness,⁵⁵ a 1998 Food and Drug Administration consumer survey showed that many consumers still practice risky behaviors, such as eating cooked meat without using a thermometer to check for the proper internal temperature.⁵⁶ Consumer research compiled by the Research Triangle Institute (RTI) for the USDA found that only 3 percent of consumers check their burgers with a food thermometer.⁵⁷ A Kansas State University focus group study also has found that nearly 30% of consumers participating preferred their hamburgers medium-rare.⁵⁸

Cooking also will not solve the problem of cross-contamination of contaminated raw ground product with other foods in the home cook's preparation area. According to the RTI report, an observational study showed that "nearly all participants cross-contaminated ready-to-eat food with

⁵⁵ FSIS, Technical Information, *Color & Cooked Ground Beef as It Relates to Doneness*, p. 1 (Aug. 1998, revised May 2000).

⁵⁶ FDA, *Keeping Food Safety Surveys Honest: Video Checks Upon on Consumer Meal Preps* (Sept.-Oct. 1999).

⁵⁷ *Checking on Changes: Consumer Research*, The Food Safety Educator, **Vol. 7**, No. 1 (2002), at p. 2 [hereinafter *Checking on Changes: Consumer Research*].

⁵⁸ Christiane Schroeter et al., *Consumer Perceptions of Three Food Safety Interventions Related to Meat Processing*, 21 Dairy, Food and Environmental Sanitation 570-81 (2001).

raw meat during meal preparation.”⁵⁹

While consumer education is clearly important, the primary burden must be on the producers of food – the slaughterhouses and grinders – to assure that the risk of contamination is eliminated before carcasses and trim are processed into ground meat.

4. The Supreme Beef Decision Provides An Additional Rationale For Implementing a Carcass and Trim Testing Regime

In December 2001, a panel of the United States Court of Appeals for the Fifth Circuit, in *Supreme Beef Processors, Inc. v. United States Dep’t of Agriculture*, determined that USDA’s *Salmonella* standard, as applied at meat grinding plants, improperly regulates the *Salmonella* levels of incoming meat.⁶⁰ Focusing on the language in section 601(m)(4) of the Federal Meat Inspection Act, which provides, among other things, that a carcass, meat or meat food produce is adulterated if it “has been prepared, packed or held under insanitary conditions . . . whereby it may have been rendered injurious to health” – the panel found that “the use of the word ‘rendered’ in the statute indicates that a deleterious change in the product must occur while it is being ‘prepared, packed or held’ owing to insanitary conditions.”⁶¹ According to the court, a condition, *i.e.* contamination, that exists before the product is prepared, packed, or held in the grinder’s establishment does not “render” the product injurious to health.⁶² As a result, the panel concluded that the performance standard does not fail because it measures *Salmonella* levels and *Salmonella* is a non-adulterant. Rather, “the performance standard is invalid because it regulates the

⁵⁹ *Checking on Changes: Consumer Research*, at p. 2.

⁶⁰ 275 F.3d 432 (5th Cir., Dec. 6, 2001).

⁶¹ 275 F.3d at 440.

⁶² 275 F.3d at 440.

procurement of raw materials.”⁶³

That decision underscores the need for **USDA** to assert its authority to regulate and monitor pathogens further upstream in the production process, in particular, at the point of slaughter, where a live animal is transformed into a carcass.

5. Carcass Testing For *E. coli* O157:H7 Would Facilitate The Acquisition Of Additional Data

Carcass testing would facilitate the acquisition of data with respect to the seasonal and geographic prevalence, if any, of the pathogen, the effectiveness of various intervention measures implemented by industry, and the relative utility of carcass sampling versus bin sampling. In short, systematic microbial testing would better enable FSIS to create a dynamic testing program that can be tailored in response to trends in the latest prevalence data.

C. An Effective Testing Program Should Incorporate Both Industry And Government Testing

FSIS Directive 10,010.1 provides guidance to its inspection personnel concerning the existing *E. coli* O157:H7 testing program in ground beef. Under the Directive, FSIS inspection personnel will not collect samples of raw-ground meat at a plant or retail outlet producing raw-ground beef products that

- initiates its own routine sampling program,
- has a certification from suppliers that the product was tested and found negative for *E. coli* O157:H7, or
- in the case of inspected plants, if the establishment uses in-plant validated pathogen-

⁶³ 275 F.3d at 441.

reduction interventions on beef carcasses.⁶⁴

This current government testing regime is deficient. Indeed, a June 2000 audit by the **USDA** Inspector General has agreed, stating that "FSIS should also expand their [sic] own testing to increase the number of tests for *E. coli* O157:H7" as well as other pathogens.⁶⁵

However, merely increasing the number of government tests on raw ground beef alone will not solve the problem. Only carcass and trim testing -- rather than further downstream in the production process -- can help identify the specific slaughter establishments that need to re-evaluate and improve their intervention strategies. While testing at the raw-ground meat plant or retail outlet may catch some *E. coli* O157:H7 positives, it does not necessarily identify which slaughterhouses need to improve their intervention strategies since the ground meat may be a mixture from numerous carcasses and several sources. Moreover, the fact that a plant uses validated pathogen-reduction interventions on beef carcasses does not assure that such interventions are working effectively on a day-to-day basis. Only industry in-plant carcass testing on a regular schedule can provide such feedback and assure that intervention strategies are effectively controlling for *E. coli* O157:H7.

Representatives of the beef-processing industry have previously proposed a carcass testing program. Under that proposal, one out of every 300 carcasses would be tested, and facilities that test carcasses on that frequency would become eligible for reduced government testing.⁶⁶ This approach is unacceptable since testing would be too infrequent and only a positive carcass would be subject

⁶⁴ USDA, FSIS Directive 10,010.1, *Microbiological Testing Program for Escherichia coli O157:H7 in Raw Ground Beef* (Feb. 1, 1998), at p. 2

⁶⁵ USDA, Office of Inspector General, *Food Safety Initiative: Meat and Poultry Products, Food Safety and Inspection Service, Implementation of the Hazard Analysis and Critical Control Point System, Report No. 24001-3-At*, (June 2000), at p. iii.

⁶⁶ *AMI, Supplemental Comments* at p. 3.

to corrective action. Rather, there should be a mandatory industry carcass-testing regime requiring plants to immediately report to FSIS any positive test results.⁶⁷ Any positive test results should trigger appropriate corrective actions.⁶⁸ Alternatively, meat from the carcass could be required to be cooked before it is sold.

In addition, where a carcass tests positive, industry should be required to step up its in-plant carcass and trim sampling to determine if the other carcasses from the same production lot have been contaminated. If such carcasses are already processed, then the plant should conduct extensive tests of raw ground and non-intact product derived from the carcasses from the same production shift if such product is available at the plant. Companies with repeated positives should be required to re-validate their interventions against *E. coli* O157:H7 and to change their slaughter processes if necessary to produce safer products.

Once the entire industry is required to perform its own testing, FSIS sampling should provide industry-wide auditing and verification, with more intensive testing focused on those plants that historically have posed the greatest risk, or those otherwise identified through *Salmonella* and generic *E. coli* testing.

IV. LEGAL BASIS FOR THE PETITION

In enacting the Federal Meat Inspection Act (FMIA), Congress gave USDA broad power to prevent the introduction of adulterated meat into commerce.⁶⁹ The FMIA is premised on a

⁶⁷ Slaughterhouses should be required to have the tests read by independent laboratories to assure that results are accurate and unbiased.

⁶⁸ These should include requiring the carcass to be reprocessed and retested before sale. Any carcass that is not reprocessed should be barred from use in ground or comminuted product.

⁶⁹ 21 U.S.C. § 601 *et seq.*

congressional finding, among other things, that “[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”⁷⁰ The courts have agreed that the purpose of this statute is to insure a high level of cleanliness and safety of meat products.⁷¹

Consistent with this purpose, meat and meat products that are “rendered adulterated” cannot be labeled, marked, stamped, or tagged as “inspected and passed.”⁷² The FMIA defines as “adulterated” any product that has been “prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”⁷³

In order to reduce the potential for product adulteration, Congress has provided USDA with broad authority to establish the sanitation requirements under which meat and poultry products are produced. Section **608** of the **FMIA** authorizes the Secretary of Agriculture to “prescribe the rules and regulations of sanitation under which [meat slaughtering and packing] establishments shall be

⁷⁰ 21 U.S.C. § 602. According to the District of Columbia Circuit, the FMIA should be construed as far as possible to have the same meaning. *Original Honey Baked Ham v. Glickman*, 172 F.3d 885, 887 (D.C. Cir. 1991).

⁷¹ *See, e.g., Original Honey Baked Ham v. Glickman*, 172 F.3d at 887 (stating that purpose of FMIA is to ensure that “meat . . . products are ‘wholesome [and] not adulterated,’ all to the end of protecting the ‘health and welfare of consumers’ and the market for wholesome and unadulterated products”); *United States v. Jorgensen*, 144 F.3d 550, 559 (8th Cir. 1998) (noting public policy underlying FMIA is that Congress has determined that the companies and people engaged in the food business have an affirmative duty to insure the food they sell to the public is safe). *See also National Pork Producers Council v. Bergland*, 631 F.2d 1353, 1361 (8th Cir. 1980) (Act authorizes USDA to ensure that products desired by consumers are made available to them “in a form and manner consistent with the public health and welfare”).

⁷² 21 U.S.C. § 608.

⁷³ 21 U.S.C. § 601(m)(4).

maintained . . .”⁷⁴ This statutory language represents a delegation by Congress to **USDA** of the power to determine the specific requirements that are necessary to assure that an establishment’s sanitation practices and conditions do not create a health risk to the human food supply. When “Congress leaves gaps . . ., either explicitly by authorizing the agency to adopt implementing regulations, or implicitly by enacting an ambiguously worded provision that the agency must interpret, it has explicitly or implicitly delegated to the agency the power to fill those gaps.”⁷⁵

With the advancement of science, USDA now has new tools and techniques available to assist in its regulation of the sanitation conditions at the facilities under its supervision, including microbiological testing. Nothing in the language of the **FMIA** specifies that USDA must use organoleptic inspection as a means to determine whether a carcass is safe and wholesome. Likewise, nothing in the statute precludes USDA from relying upon the advancements of science in fulfilling its mandate to assure that food products are not adulterated, including the ability to conduct microbiological testing for pathogens of concern. Indeed, “[r]egulatory or enforcement authority generally carries with it all the modes of inquiry and investigation traditionally employed or *useful* to execute the authority granted.”⁷⁶

Verifying, through microbiological testing, that slaughter plants are employing effective control strategies and sanitation procedures to prevent or reduce contamination of carcasses with *E.*

⁷⁴ 21 U.S.C. § 608. *See also* 21 U.S.C. § 621 (stating that the Secretary “shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter,” including rules on sanitation).

⁷⁵ *National Fuel Gas Supply Corp. v. FERC*, 811 F.2d 1563, 1569 (D.C. Cir. 1987). *See also Philadelphia Television Broadcasting Co. v. FCC*, 359 F.2d 282, 284 (D.C. Cir. 1966) (Where Congress has delegated to an agency the principal role in implementing a statute, the agency “is entitled to some leeway in choosing . . . which regulatory tools will be most effective in advancing the Congressional objective”).

⁷⁶ *Dow Chemical Co. v. United States*, 476 U.S. 227, 233 (1986) (emphasis added).

coli O157:H7 would represent a reasonable exercise of USDA's delegated authority under the FMIA. The overall goal of the FMIA is to assure the safety of meat and meat products. Testing of carcasses and trim is wholly consistent with that purpose since it helps assure that products are not being processed under sanitary conditions that could lead to product adulteration, particularly through cross-contamination. Reading FMIA section 608 as authorizing FSIS to test raw carcasses for *E. coli* O157:H7 also is consistent with the general rule that regulatory statutes intended to protect the public health should be construed broadly to effect their regulatory purpose.⁷⁷

The Fifth Circuit's decision in *Supreme Beef* does not prevent FSIS from instituting a carcass testing regime.⁷⁸ In contrast to Salmonella, *E. coli* O157:H7 is legally an adulterant in ground and other non-intact raw beef products.⁷⁹ FSIS has broad precautionary authority under the FMIA to treat *E. coli* O157:H7 as an adulterant even if the beef contaminated with such bacteria would be injurious to health only if improperly cooked.⁸⁰ The greatest potential exists at slaughter for one *E. coli* O157-infected beef carcass to infect other carcasses passing through the same line and to infect a whole trim box or combo bin when that carcass or trim is ground into hamburger and mixed with other meat.

The consumer-protection mandates of the FMIA can be fully implemented only by using the best-available means, including those provided by modern science, to protect the public from adulterated meat. Although grinders should implement process and distribution controls that reduce public health concerns associated with ground beef contaminated with *E. coli* O157:H7, avoidance

⁷⁷ *United States v. Sellers*, 926 F.2d 410, 416 n.2 (5th Cir. 1991).

⁷⁸ 275 F.3d 432 (5th Cir. 2001).

⁷⁹ *Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994).

⁸⁰ *Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994).

or minimization of contamination at every stage of the fabrication process is a critical element in public health protection – particularly in the case of raw beef carcasses where microbiological pathogens, once present, can readily multiply and spread to uncontaminated meat.

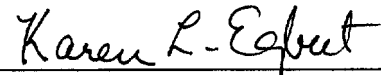
IV. CONCLUSION

The current system where FSIS only conducts limited-random sampling for *E. coli* O157:H7 in raw ground beef and asks companies to recall the affected products when it is found in food must be converted to one that is more systematic, more prevention-oriented, and one that gives consumers greater assurance that it is actually catching the hazards in the food supply posed by this pathogen. FSIS should implement a new testing regime in addition to the existing program of testing raw ground meat. Under the new program, slaughterhouses should be required to conduct microbial testing of carcasses and trimmings for the presence of *E. coli* O157:H7. As part of this new testing regime, FSIS also should expand the current federal testing of raw ground beef products to include carcasses and trim to verify that slaughterhouses are using effective intervention strategies. Until pre-harvest safety programs can eliminate the threat of *E. coli* O157:H7 through vaccination of cattle or some other technique, testing of carcasses and trimmings must be part of an integrated strategy for controlling and reducing the threat of this dangerous pathogen in beef.

V. Certification

The undersigned parties certify that, to their best knowledge and belief, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petition which are unfavorable to the petition.

Respectfully submitted,



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MEMBERS OF SAFE FOOD COALITION:

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