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Margaret O’K. Glavin, Acting Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
14th Street and Independence Ave. S.W.
Room 331-E
Washington, D.C. 20250

CITIZEN PETITION

I. Introduction

On behalf of the Center for Science in the Public Interest (CSPI), Consumers Union and the Consumer Federation of America, we submit this petition requesting the Food Safety and Inspection Service (FSIS) to publish a *Campylobacter jejuni* performance standard for raw poultry.¹

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*. Consumer Federation of America (CFA) is an association of approximately 285 pro-consumer groups formed in 1968 to advance the consumer interest

¹ CSPI and CFA are members of the Safe Food Coalition, an informal group of consumer, public health, whistle blower, senior citizen and labor organizations that work to educate the public about the hazards of foodborne illness and seek congressional and administrative action to improve meat, poultry, and seafood inspection.

through advocacy and education. CFA's positions are determined by its members and by its board of directors. Consumers Union (CU) is a nonprofit membership organization chartered to provide consumers with information, education and counsel about goods, services, health and personal finance. CU's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees.

II. Action Requested

We request that FSIS establish a pathogen reduction performance standard for *Campylobacter jejuni* in raw poultry products. Since the early 1970s, *Campylobacter* has been recognized as one of several bacterial sources of gastrointestinal illness in humans. It has been characterized by epidemiological and clinical investigations as the leading cause of sporadic foodborne bacterial infection in the United States.² Of the various species of *Campylobacter*, *Campylobacter jejuni* (*C. jejuni*) has been isolated from 99 percent of the human campylobacteriosis cases.³ Foodborne illnesses attributable to this bacteria have resulted in substantial health care costs and lost productivity and have been estimated to cost \$1.2 billion per year.⁴

Pathogen reduction is an important element of the FSIS food-safety strategy. Under the Hazard Analysis and Critical Control Point (HACCP) program, FSIS inspection has changed its

² Food and Drug Administration, Center for Food Safety & Applied Nutrition, *Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook*, Chapter 4, *Campylobacter jejuni* [hereinafter *Bad Bug Book*] <<http://www.cfsan.fda.gov/~mow/chap4.htm>>.

³ Robert V. Tauxe, *Epidemiology of Campylobacter jejuni Infections in the United States and Other Industrialized Nations*, Chapter 2, 9-19, in I. Nachamkin, et al. eds., *CAMPYLOBACTER JEJUNI: CURRENT STATUS AND FUTURE TRENDS* (1992), reprinted by the U.S. Department of Health and Human Services [hereinafter Tauxe, *Epidemiology*].

⁴ Stephen R. Crutchfield & Tanya Roberts, *Food Safety Efforts Accelerate in the 1990's*, 23 *Food Review* 44-49 (Sept.-Dec. 2000) [hereinafter Crutchfield & Roberts, *Food Safety Efforts Accelerate*].

emphasis from catching adulterated products before they leave plants to confirming and verifying that a plant's sanitation and process control systems are working properly to prevent adulteration. The *Salmonella* testing program implemented under HACCP has been successful in reducing the rates of that pathogen by 50% in most poultry plants.

FSIS has estimated that between 60 and 80 percent of post-chill whole chickens sampled at processing facilities are contaminated with *Campylobacter*.⁵ Without a performance standard for *Campylobacter*, neither government nor industry can be assured that establishments' HACCP programs are effectively controlling for this pathogen in poultry processing. Establishing a pathogen reduction standard is especially appropriate in light of the fact that new anti-microbial treatments have been demonstrated to successfully lower the levels and prevalence of pathogens on poultry, including *Campylobacter*.⁶

FSIS has been actively collecting baseline prevalence information about *Campylobacter* in poultry since 1994. Over two years ago, in August 1999, FSIS established a *Campylobacter* Performance Standard Docket committee to explore options, including a performance standard, that could accomplish the public health objective of reducing campylobacteriosis associated with the consumption of contaminated poultry. In those two years, *Campylobacter* has continued to contaminate poultry at high rates, and Americans have continued to become ill from eating contaminated poultry. FSIS should protect the public health by promulgating a performance standard for this pathogen. Establishing a performance standard for *Campylobacter* to promote

⁵ 65 Fed. Reg. 75,187, 75,190 (Dec. 1, 2000).

⁶ See 65 Fed. Reg. at 75,189 (discussing commercial plant trials demonstrating the efficacy of a trisodium phosphate (TSP) rinse with a chlorine rinse in reducing prevalence of *Campylobacter* from 78.6 percent to 41.6 percent).

industry-wide adoption of pathogen control practices and technologies is the single best way to protect the public against this common cause of foodborne gastrointestinal illness.

III. Statement of Grounds For Petition

A. *Campylobacter* Is A Major Cause Of Foodborne Bacterial Illness And Therefore A Public Health Concern

1. *Campylobacter* Sickens More Americans Than Any Other Foodborne Pathogen

Campylobacter, commonly found in the intestinal tracts of cats, dogs, poultry, wild birds, and cattle, was first recognized as a cause of human foodborne illness in the early 1970's. Today, it is estimated that *Campylobacter* causes approximately 1.9 million foodborne illnesses, resulting in 10,539 hospitalizations and 100 deaths nationwide each year.⁷ Studies show that consuming as few as 500 *Campylobacter* bacteria can cause an infection, known as campylobacteriosis.⁸ Most infections cause diarrheal illness and other symptoms, such as fever, abdominal cramping, nausea, headache, and muscle pain that do not require hospitalization.⁹

However, this pathogen also has been linked to serious invasive illnesses, such as bacteremia and septic arthritis,¹⁰ as well as hemolytic uremic syndrome (HUS), meningitis, endocarditis, and abortion in pregnant women. Antibiotic therapy may be required for patients with more serious manifestations of illness.

⁷ Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 Emerging Infectious Diseases 607-25, at p. 611 (Sept.-Oct. 1999) [hereinafter *Food-Related Illness and Death*].

⁸ FSIS, Backgrounder, *Campylobacter Questions and Answers*, at p. 1 (Nov. 1997).

⁹ *Bad Bug Book*, Chapter 4.

¹⁰ Sean F. Altekruze, et al., *Campylobacter jejuni - An Emerging Foodborne Pathogen*, 5 Emerging Infectious Diseases 28-35, at pp. 28-29 (Jan.- Feb. 1999) [hereinafter Altekruze, *Campylobacter jejuni - An Emerging Foodborne Pathogen*].

Campylobacter infections also can trigger development of Guillain-Barré Syndrome, a rare but serious form of acute neuromuscular paralysis. According to the Centers for Disease Control (CDC), as many as 40% of Guillain-Barré syndrome cases in this country may be triggered by *Campylobacter* infections.¹¹ Although even a healthy person can become ill from a *Campylobacter* infection, persons with chronic illnesses and compromised immune systems, including people with HIV, have higher infection rates and are more susceptible to serious health complications from campylobacteriosis.¹²

The Centers for Disease Control and Prevention (CDC) estimate that in 1999, *Campylobacter* caused approximately 3,884 of the 10,248 bacterial infections by foodborne pathogens in the seven states under surveillance by FoodNet, the population-based active surveillance network of foodborne illnesses.¹³ Of the 59 deaths documented by FoodNet in 1999, five were due to *Campylobacter*.¹⁴

Although the incidence of *Campylobacter* infections declined in 1998 and 1999, after increases in 1996 and 1997,¹⁵ it increased again in 2000.¹⁶ *Campylobacter* still is responsible for

¹¹ Centers for Disease Control & Prevention, Division of Bacterial and Mycotic Diseases, *Campylobacter Infections*.

¹² Sean F. Altekruise, et al., *Campylobacter jejuni*, 14 *Microbial Food Borne Pathogens*, at 33 (Mar. 1998).

¹³ Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 1999 (Final Report)*, Narrative Report (Nov. 2000), at p. 7 [hereinafter *FoodNet Surveillance Report for 1999*].

¹⁴ *FoodNet Surveillance Report for 1999*, at p. 12.

¹⁵ *FoodNet Surveillance Report for 1999*, at pp. 4-5.

¹⁶ Centers for Disease Control and Prevention, *Preliminary FoodNet Data on the Incidence of Foodborne Illnesses – Selected Sites, United States 2000*, 50 *Morbidity and Mortality Weekly Report* 241-46 (Apr. 6, 2001), at Table 1 [hereinafter CDC, *Preliminary 2000 FoodNet Data*].

more illnesses than any other foodborne pathogen in the United States, including *Salmonella*,¹⁷ causing an estimated 1.9 million foodborne illnesses, 10,539 hospitalizations and almost 100 deaths each year.¹⁸ It appears that *Campylobacter*-related illnesses are significantly under-reported, because the majority of illnesses caused by *C. jejuni* are sporadic rather than associated with large outbreaks or epidemics.

The costs related to food-borne *Campylobacter* infections are significant. The annual foodborne costs of *Campylobacter*-related illness is an estimated \$1.2 billion.¹⁹ Moreover, the costs associated with the chronic conditions associated with *Campylobacter* “would be substantially increased if willingness to pay to avoid disability, pain, and suffering were also taken into account.”²⁰

2. *Campylobacter* Is Prevalent In Poultry

Foods of animal origin, including poultry, meat, and raw milk are significant sources of human *Campylobacter* infection.²¹ *Campylobacter* organisms are found in the farm environment and many healthy chickens carry the organism in their intestinal tracts, ceca, and in the crop, an internal organ.²² The precise source of infection has not been identified but is believed to be

¹⁷ *FoodNet Surveillance Report for 1999*, at p. 17; CDC, *Preliminary 2000 FoodNet Data*, at Table 1. See also Altekruze, *Campylobacter jejuni - An Emerging Foodborne Pathogen* at 28 (finding that *Campylobacter jejuni* is the most commonly reported bacterial cause of foodborne infection in the United States).

¹⁸ *Food-Related Illness and Death*, at p. 611.

¹⁹ Crutchfield & Roberts, *Food Safety Efforts Accelerate* at 49 (uses year 2000 dollars).

²⁰ Crutchfield & Roberts, *Food Safety Efforts Accelerate* at 48-49.

²¹ Altekruze, *Campylobacter jejuni – An Emerging Foodborne Pathogen* at 32.

²² USDA, Agricultural Research Service, *Incidence of Campylobacter in Crops of Pre-Harvest Market-Age Broiler Chickens*, Poultry Science [Publication request, Dec. 16, 1997] [hereinafter ARS, *Incidence of Campylobacter*].

associated with certain environmental factors, such as unchlorinated water, beetles, wild birds, and rodents.²³ Farm practices, such as thinning of flocks prior to slaughter, and transfer from farm workers' boots and clothing also are potential sources of contamination.²⁴ Once *Campylobacter* enters the chicken house, it spreads very rapidly and infects virtually all the birds. The stresses associated with transporting the poultry to slaughter also have been shown to substantially increase pathogen populations in fecal material which can be transferred to the carcass exterior, increasing the risk that contaminated poultry will reach the consumer.²⁵

During slaughter, *C. jejuni* from the intestinal contents of the birds can spread to the carcass and plant machinery. Cross-contamination can occur at many points as bacteria spreads from carcasses to hands of workers, equipment and utensil surfaces and from them to other carcasses.²⁶ Rupture of the crop during processing also can spread the bacteria to the chicken carcass.²⁷

Although the first major processing step, the scald tank, can lower *Campylobacter* levels depending on the water temperature used, one scientific review has found that the scalding process also opens up feather follicles to aid feather removal, and that “the follicles remain open

²³ Altekruze, *Campylobacter jejuni – An Emerging Foodborne Pathogen* at 31-32.

²⁴ J.E. Corry & H.I. Atabay, *Poultry as a Source of Campylobacter and Related Organisms*, 30 Symposium Ser Soc. Applied Microbiology 96S-114S (2001); *Campylobacter in Broilers*, Current Concepts in Broiler Production, at p. 1 (Spring 2000). New research has indicated that a major source of *Campylobacter* may be the fertile chicken egg. USDA, ARS, *Solving the Campylobacter Mystery*, Agricultural Research Magazine, at pp. 8-9 (June 2001). <<http://www.ars.usda.gov/is/AR/archive/jun01/campy0601.htm>>.

²⁵ P. Whyte, et al., *The Effect of Transportation Stress on Excretion Rates of Campylobacters in Market-Age Broilers*, 80 Poultry Science 817-20 (2001).

²⁶ Bryan & Doyle, *Health Risks and Consequences* at 335.

²⁷ ARS, *Incidence of Campylobacter*, Interpretive Summary.

throughout processing until chilling when they close, thereby retaining microorganisms.”²⁸

Mechanical defeathering (picking or plucking) with rubber fingers is a major source of contamination, particularly because fingers are not cleaned between each bird. The rubber fingers also beat bacteria into the pores, crevices and folds of the poultry skin. According to one report, “[p]athogen populations on the finished packaged product often reflect the contamination present immediately after picking.”²⁹ Evisceration also is a point where cross-contamination to previously uncontaminated carcasses can occur, particularly if the intestines are cut.³⁰ One study of evisceration using tracer bacteria on one bird showed that the next 42 birds were contaminated with the tracer bacteria and that there was sporadic contamination up to the 150th bird.³¹

That *Campylobacter* is a significant concern is demonstrated by the fact that FSIS has estimated that between 60 and 80 percent of chilled whole birds sampled at processing facilities are contaminated with *Campylobacter*.³² A nationwide broiler chicken microbiological baseline data survey between July 1994 and June 1995 showed that *Campylobacter jejuni/coli* was recovered from 88.2% of broiler carcasses.³³ While a more recent survey showed a decreased prevalence of *Campylobacter* in young chickens tested between January and June 1999,

²⁸ Bryan & Doyle, *Health Risks and Consequences*, at 330, 334.

²⁹ Bryan & Doyle, *Health Risks and Consequences* at 334.

³⁰ Ann Marie McNamara, National Advisory Committee on Microbiological Criteria for Foods, Generic HACCP Application in Broiler Slaughter and Processing, *Microbiological Profile of Raw Chickens*, 60 *Journal of Food Protection* 579-604, p. 586 (1997).

³¹ Bryan & Doyle, *Health Risks and Consequences* at 335.

³² 65 Fed. Reg. at 75,190.

³³ USDA, FSIS, *Nationwide Broiler Chicken Microbiological Baseline Data Collection Program, July 1994-June 1995*, Executive Summary (April 1996), p. 1 [hereinafter FSIS, *Nationwide Broiler Chicken Microbiological Baseline Data*]. <<http://www.fsis.usda.gov/OPHS/baseline/contents.htm>> .

Campylobacter was still present on 75% of the young chickens tested – an unacceptably high percentage.³⁴ FSIS *Campylobacter* monitoring data on all classes of raw whole chicken carcasses sampled between October 1998 to June 1999, showed a 78.4 percent prevalence.³⁵ These *Campylobacter* levels are also being confirmed by retail surveys.

A study, conducted at fifty-nine stores from four different retail chains over a 14-month period between June 1999 and July 2000, in the Washington, D.C. area showed that the majority of raw chicken samples (70.7%) were contaminated with *Campylobacter* and that 91% of the stores visited had *Campylobacter*-contaminated chickens.³⁶ In addition, a survey of Minnesota raw chicken products sold at retail reported that 88% carried *Campylobacter* and 74.1% carried *C. jejuni*.³⁷ *Campylobacter* also is prevalent on turkeys. An FSIS study done between 1996 and 1997 showed that 90.3% of processed turkeys tested positive for *Campylobacter*.³⁸

3. *Campylobacter* On Poultry Causes A High Proportion Of Sporadic Foodborne Illness

While cooking will kill *Campylobacter*, cross-contamination of other foods with drippings

³⁴ USDA, FSIS, Memorandum Re: *Campylobacter* Program Update from Gerri Ransom, Acting Director Microbiology Division, OPHS to Michael Micchelli, Program Analyst, Evaluation and Analysis Division, OPPDE (Sept. 8, 1999) (providing the National Advisory Committee on Meat and Poultry Inspection with FSIS *Campylobacter* Program Update), p. 4 (Table) [hereinafter *Ransom Memorandum*]. The data appears to show a higher prevalence during summer and autumn months and a decrease in prevalence during the winter and spring months. *Id.* at 2.

³⁵ *Ransom Memorandum*, at 4 (Table).

³⁶ Cuiwei Zhao, et al., *Prevalence of Campylobacter spp., Escherichia coli, and Salmonella Serovars in Retail Chicken, Turkey, Pork, and Beef from the Greater Washington, D.C. Area*, 67 *Applied and Environmental Microbiology* 5431-5436 (Dec. 2001) [hereinafter Zhao, *Prevalence of Campylobacter spp.*].

³⁷ Kirk E. Smith, et al., *Quinolone-Resistant Campylobacter jejuni Infections in Minnesota, 1992-1998*, 340 *New England Journal of Medicine* 1525-1532 (May 20, 1999), at 1529 [hereinafter Smith, *Quinolone-Resistant Campylobacter*].

³⁸ USDA, FSIS, *Nationwide Young Turkey Microbiological Baseline Data Collection Program, August 1996-July 1997*, Executive Summary (1998), <<http://www.fsis.usda.gov/OPHS/baseline/yngturk.pdf>>.

from raw poultry and the consumption of undercooked poultry have been identified as the leading risk factors for human campylobacteriosis³⁹ and the predominant causes of sporadic cases of *Campylobacter* infections.⁴⁰ It is estimated that up to 70 percent of sporadic cases involve consumption of contaminated poultry.⁴¹

Campylobacter on the skin of chicken rarely multiplies during thawing. However, it can multiply if thawed poultry is left either at room temperature or in a water bath for several hours.⁴² As thaw water accumulates in packaging and seeps to table, pan, refrigerator shelves or sinks, it can cross-contaminate other foods prepared on or in contact with the same surface.⁴³ Indeed, “indirect transfer of *C. jejuni* from raw poultry to salads and prepared foods is a more common means of disseminating this pathogen in kitchens than cooked poultry that has been left at room temperature or refrigerated in large masses and inadequately reheated.”⁴⁴

Most *Campylobacter*-related illnesses are isolated, sporadic cases that never get reported to states and the CDC as outbreaks.⁴⁵ Because campylobacteriosis is seen more as sporadic cases, and sporadic cases are rarely reported to doctors or state and federal health officials, it is

³⁹ Altekruze, *Campylobacter jejuni - An Emerging Foodborne Pathogen* at p. 31.

⁴⁰ Tauxe, *Epidemiology*, at 15-16.

⁴¹ Irene V. Wesley, *Overview: Public Health Significance of Campylobacter in Livestock and Poultry*, 1998 Proceedings, United States Animal Health Association, at p. 4 <<http://www.usaha.org/speeches/speech98/s98wesle.html>>.

⁴² Bryan & Doyle, *Health Risks and Consequences* at 336.

⁴³ Bryan & Doyle, *Health Risks and Consequences* at 336.

⁴⁴ Bryan & Doyle, *Health Risks and Consequences* at 329.

⁴⁵ FDA, Center for Veterinary Medicine, *Risk Assessment on the Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken* (Oct. 18, 2000, rev'd Jan. 5, 2001), section 1, p. 1-7 (stating that 99% of all *Campylobacter* cases are sporadic).

highly likely that there is significant under-reporting of illness due to consumption of poultry. Although most cases are sporadic in nature, there also have been outbreaks as a result of consumption of undercooked poultry and cross-contamination of foods with raw poultry. For instance, in one outbreak in Oklahoma in 1996 affecting 14 people, the investigative report concluded that the *Campylobacter jejuni* infections that occurred were most likely acquired from eating lettuce cross-contaminated with raw chicken.⁴⁶ At least 3 outbreaks, resulting in 123 *Campylobacter*-related foodborne illnesses, have been attributed to the consumption of poultry since 1990.⁴⁷

The National Chicken Council has reported that the consumption of chicken, including broilers, has been rising steadily and has estimated the per capita consumption by 2002 will be 81.5 pounds/year.⁴⁸ Per capita consumption of turkey is also predicted to rise by 2002 to 18.7 pounds/person each year.⁴⁹ As consumer consumption of poultry rises, it is likely that the number of *Campylobacter*-related infections from poultry will increase as well. Adoption of a performance standard not only would help to reduce the number of *Campylobacter*-related illnesses, it would also help assist in meeting the Healthy People 2010 Objective for

⁴⁶ CDC, *Outbreak of Campylobacter Enteritis Associated with Cross-Contamination of Food – Oklahoma, 1996*, 47 MMWR Weekly 129-131 (Feb. 27, 1998),

⁴⁷ CSPI, *Outbreak Alert!* (updated Oct. 2001), at 39.

⁴⁸ National Chicken Council and U.S. Poultry & Egg Association, *Statistics: Per Capita Consumption of Poultry and Livestock, in Pounds, 1960 to Estimated 2002*, <http://www.eatchicken.com/statistics/consumption_pounds_60-02.cfm>.

⁴⁹ Meat & Poultry Magazine, *State of the Species: Turkey* (Sept. 1, 2001) (citing USDA statistics), <<http://www.meatpoultry.com/articlearchives/archive-article.asp?chkArticle+46939>>.

Campylobacter of reducing the number of infections by 50% from the 1997 baseline.⁵⁰

B. A Pathogen-Reduction Standard For *Campylobacter* Is Necessary to Protect Consumers

1. A *Campylobacter* Standard Is Necessary for Effective HACCP Implementation

The goal of the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) system, adopted in 1996, is to reduce the risk of foodborne illness from meat and poultry products to the maximum extent possible by ensuring that appropriate and feasible preventative and corrective measures are taken at each stage of the food production process where food safety hazards occur.⁵¹ Since the initiation and implementation of HACCP, FSIS has viewed performance standards as an integral part of its regulatory strategy for improving food safety. The agency has emphasized that “[p]athogen-specific performance standards for raw products are an essential component of the FSIS food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products.”⁵² FSIS also has explained that “[p]erformance standards tell establishments what degree of effectiveness their HACCP plans will be expected to achieve and provide a necessary tool of accountability for achieving acceptable food safety

⁵⁰ *Healthy People 2010*, Objective 10-1, *Campylobacter* infections (stating goal to reduce number of cases from 1997 baseline of 24.6 cases/ per 100,000 people by 50% to 12.3 cases/100,000 people).

⁵¹ 61 Fed. Reg. at 38,817.

⁵² 61 Fed. Reg. 38,806, 38,812 (July 25, 1996). See also 64 Fed. Reg. 732, 735 (Jan. 6, 1999) (stating that “FSIS has determined that HACCP-based process controls combined with appropriate food safety performance standards are the most effective means available for controlling and reducing harmful bacteria on meat and poultry products”).

performance.”⁵³ They also afford establishments greater flexibility and autonomy in setting up science-based process controls over pathogens.⁵⁴

When it adopted the performance standard for *Salmonella* as part of the pathogen reduction program, FSIS indicated that this was only a “first step” in what the agency anticipated would be a broader reliance in the future on pathogen-specific performance standards to reduce the incidence of foodborne illnesses associated with harmful bacteria on raw meat and poultry products.⁵⁵ Yet, FSIS has not adopted any additional performance standards for raw poultry.

One of the goals of poultry processing should be to keep microbiological contamination to a minimum. Because *Campylobacter* can be reintroduced at different stages during processing, a performance standard for this pathogen would assist industry in identifying and monitoring major points on the production line where cross-contamination is most likely to occur and provide incentives to producers to develop and implement the most effective pathogen intervention treatments at different processing stages.⁵⁶

In written testimony before the Senate Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies, then-FSIS Administrator Thomas J. Billy noted that in Fiscal Year 2000, FSIS completed the baseline testing for *Campylobacter* in raw chicken carcasses and that the establishment of baseline profiles “will provide a yardstick for measuring

⁵³ 61 Fed. Reg. at 38,811.

⁵⁴ 61 Fed. Reg. at 38,808.

⁵⁵ 61 Fed. Reg. at 38,836.

⁵⁶ J.E.L. Corry & H.I. Atabay, *Poultry as a Source of Campylobacter and Related Organisms*, 90 Journal of Applied Microbiology 96S-114S (June 2001).

the effectiveness of [HACCP] changes over time.”⁵⁷ Nonetheless, FSIS has not acted to adopt criteria or standards for judging whether an establishment’s HACCP plan and sanitation measures are dealing effectively with the food safety hazard posed by *Campylobacter* at each processing stage and achieving reductions in that specific pathogen. Adoption of a pathogen reduction standard would provide for uniformity in the adoption and implementation of HACCP. In addition, implementation of a performance standard for *Campylobacter* would assist FSIS in its oversight role and in verifying that establishments’ HACCP systems are effective and working as intended. Finally, and most importantly, adoption of a *Campylobacter* performance standard will help protect the public’s health.

i. The *Salmonella* Standard Has Not Worked To Achieve Reductions In *Campylobacter*.

Recognizing that performance standards provide an objective means of verifying that meat and poultry establishments are achieving acceptable levels of food safety performance, FSIS established a pathogen-reduction standard for *Salmonella* in 1996 when it promulgated the HACCP rule.⁵⁸ In selecting *Salmonella*, FSIS explained that, among other things, some intervention strategies and process controls that result in reductions in *Salmonella* would be expected to result in reductions of other pathogens found in the intestines of animals.⁵⁹

Through mandatory HACCP and *Salmonella* performance standards for meat and poultry

⁵⁷ FSIS, Communications to Congress, *Statement of Thomas J. Billy, Administrator, before the Senate Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies on the Current Status of Food Safety and Inspection Service (FSIS) Programs and the FY 2002 Budget for Food Safety Within the U.S. Department of Agriculture*, (Apr. 26, 2001), <<http://www.fsis.usda.gov/OA/congress/record042601.htm>>.

⁵⁸ 61 Fed. Reg. at 38,835.

⁵⁹ FSIS, Background, *The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems*, pp. 7-8 (July 1996), <<http://www.fsis.usda.gov/oa/background/finalrul.htm>>.

products, USDA has seen significant reductions in *Salmonella* levels in all product categories.⁶⁰ Based on two years of testing data between January 1998 and January 2000 in the large poultry plants that implemented HACCP in January 1998, the prevalence of *Salmonella* is significantly lower than earlier baseline studies. In broiler carcasses for example, 20% tested positive for *Salmonella* before HACCP implementation, compared to 10.3 percent since implementation -- a decline of almost 50%.⁶¹ In small plants, 20% of broilers tested positive for *Salmonella* in pre-HACCP baseline studies, while 16.3% tested positive after one year of HACCP implementation.⁶²

The large decreases in *Salmonella* contamination do not, however, appear to have resulted in correspondingly large decreases in the prevalence of *Campylobacter* on poultry. A study of Washington, D.C.-area retail establishments, which measured prevalence of both *Campylobacter* and *Salmonella* on raw poultry sold at retail, showed that *Campylobacter* is present at much higher rates than *Salmonella* – 70.7% of chicken samples tested positive for *Campylobacter*, while only 4.2% tested positive for *Salmonella*.⁶³ A recent study of turkeys has shown that a higher percentage of turkeys had *Campylobacter* in their droppings than *Salmonella*.⁶⁴ For instance, at 15 weeks of age, 80% of turkey hens tested positive for *Campylobacter* compared to

⁶⁰ U.S. Department of Agriculture, FSIS News Release, *FSIS Reports Continued Decline of Salmonella* (Mar. 21, 2000), <<http://www.fsis.usda.gov/OA/news/2000/salmrel2.htm>>.

⁶¹ FSIS, Backgrounder, *Progress Report on Salmonella Testing of Raw Meat and Poultry Products* (Mar. 2000), Table 1 [hereinafter *Progress Report on Salmonella Testing*], <www.fsis.usda.gov/oa/background/salmtest5/htm>.

⁶² *Progress Report on Salmonella Testing* at Table 3.

⁶³ Zhao, *Prevalence of Campylobacter spp.*, at p. 5433.

⁶⁴ N.A. Cox, et al., *Prevalence of Campylobacter and Salmonella in the Cecal Droppings of Turkeys During Production*, 9 *Journal of Applied Poultry Research* 542-45 (2000) [hereinafter Cox, *Prevalence of Campylobacter*].

13% for *Salmonella*.⁶⁵

These data show that intervention strategies – both on-farm and at the processing plant -- that are working to control and reduce *Salmonella* are not achieving similar reductions in the prevalence of *Campylobacter*.⁶⁶ The continued high prevalence of *Campylobacter* on raw poultry while *Salmonella* rates are declining is evidence of a general failure to control for *Campylobacter* at all stages of the production process. FSIS’s prior statements that there are “insufficient data” to establish a *Campylobacter* standard, echoing comments made by the National Advisory Committee for Microbiological Criteria for Foods about the “paucity of data on the relationship among *Campylobacter*, other microorganisms . . . and poultry,” are no longer valid.⁶³ Concern about the lack of data defining its relationships to other pathogens does not speak to the capability of, or need for, establishing a *Campylobacter* reduction standard. In light of the clear public health impacts from this pathogen, there is no justification for delay. Therefore, FSIS should establish a performance standard for *Campylobacter* in raw poultry products.

ii. A Standard Should Be Quantitative, Not Qualitative

Using the updated June 2000 nationwide prevalence data as a baseline, FSIS should establish a percentage reduction in *Campylobacter* that all establishments slaughtering and processing raw poultry must achieve. The standard should be based on the lowest incidence of

⁶⁵ Cox, *Prevalence of Campylobacter*.

⁶⁶ For instance, one study has found that treating the feed of broiler chickens with dried yeast resulted in reduced frequency of *Salmonella* colonization, but that *Campylobacter* levels were not significantly reduced by yeast treatment. See Eric Line, et al., *Yeast Treatment to Reduce Salmonella and Campylobacter Populations Associated With Broiler Chickens Subjected to Transport Stress* [Abstract], USDA, Agricultural Research Service, (Updated Dec. 18, 1998).

⁶³ 65 Fed. Reg. at 75,190-91.

Campylobacter contamination that establishments can achieve by application of the best available control and intervention technologies, not on a lot-by-lot basis, but consistently over a period of time – whatever that level may be.

A quantitative standard is the only one that provides an objective basis to verify an establishment's controls over processes where contamination is most likely to occur and assures across-the-board consistency in pathogen reduction. If qualitative standards are used, then acceptable pathogen loads could vary among carcasses and among plants. By contrast, quantitative standards help level the playing field for industry by providing clear, consistent guidelines within which to operate. They provide all processors with the same targets and provide government inspectors with consistent inspection criteria, and would protect the public health.

A quantitative limit also provides incentives for processing facilities to purchase the cleanest birds possible. This is especially important in reducing overall contamination levels since farm contamination is major source of entry for *Campylobacter* into the processing plant.

iii. An Effective Standard Must Be Accompanied By Testing

To be truly effective, a pathogen-reduction standard must be accompanied by a dual government and industry testing regime. Development of new, fast tests for identifying *C. jejuni* should aid in implementing a performance standard.⁶⁴ Among other things, such testing would assist industry in evaluating the efficacy of various pathogen-intervention measures and facilitate government acquisition of data concerning the prevalence of *Campylobacter* as a function of

⁶⁴ See USDA, Agricultural Research Service, *Fast Tests for Campylobacter* (March 1999), <<http://www.ars.usda.gov/is/AR/archive/mar99/campy0399.htm>>. See also FSNet (Oct. 18, 2001), *Researchers Study Pathogens on Raw Poultry*, reported in Meat News (Oct. 17, 2001).

product type, season, and geography.

Testing results should trigger appropriate corrective actions by the company. FSIS should carefully review data from industry testing to identify and investigate persistent problems.

Companies with repeated positives should be required to re-validate their interventions and to change their slaughter processes if necessary to produce safer products.

FSIS should conduct a random-sampling program as an additional layer of protection against the distribution of contaminated products and to better enable the agency to independently evaluate the efficacy of plants' process controls. If a company repeatedly violates both the *Campylobacter* and the *Salmonella* standards, then FSIS should consider enforcement action, which could mean withdrawing inspection and shutting down the facility.

Initially, FSIS should target establishments that do not conduct their own testing and/or do not employ validated interventions against *Campylobacter*. However, once the entire industry is performing its own testing, FSIS sampling should be focused on those plants and products that historically have posed the greatest risk. Once industry testing is fully implemented, all plants should be subject to random government testing in a system similar to the one used for *Salmonella* testing under the pathogen reduction/HACCP rule.

2. A Performance Standard Would Encourage Innovation In Control Of *Campylobacter*

FSIS has repeatedly emphasized that it is the responsibility of industry to produce safe food products. Neither government nor industry should rely on consumers to cook the problem away. In 1996, CSPI pointed out that this “strategy has not been effective from a public health

standpoint.”⁶⁵ As the data shows, *Campylobacter* is still prevalent at high levels in raw chicken and consumers are still being sickened. A *Campylobacter* performance standard would encourage industry to adopt new and more efficacious control measures and pathogen-lowering strategies targeted specifically for *Campylobacter*.

In 1996, FSIS amended its poultry products inspection regulations to add anti-microbial agents as a new class of substances for use on poultry products and to include trisodium phosphate (TSP) as an approved anti-microbial agent on raw, chilled poultry carcasses.⁶⁶ Trial tests of anti-microbial treatments using TSP have proven effective in reducing prevalence and levels of *Campylobacter* as well as other pathogens on raw, chilled poultry carcasses.⁶⁷ In particular, these trial tests have demonstrated that use of such rinses can reduce *Campylobacter* prevalence from 78.6 to 41.6 percent, a 37 percent reduction.⁶⁸ Other techniques for reducing pathogens include air chilling, used in Europe and Canada, and steam pasteurization. While each of these techniques must be subjected to further study to confirm not only their effectiveness in reducing the prevalence of *Campylobacter* but their safety for use on human food, adopting a *Campylobacter* performance standard would provide an incentive for industry to adopt new techniques, while leaving each individual plant free to adopt plant-by-plant approaches for reducing bacterial loads of *Campylobacter*. Moreover, new research may provide methods for identifying specific strains of *Campylobacter* so that specific techniques can be developed for

⁶⁵ CSPI, *Playing Chicken: The Human Cost of Inadequate Regulation of the Poultry Industry*, at p. 4 (Mar. 1996).

⁶⁶ 9 C.F.R. § 424.21(c).

⁶⁷ 65 Fed. Reg. at 75,189.

⁶⁸ 65 Fed. Reg. at 75,189.

each one, if necessary.

3. A Pathogen Reduction Standard Is Needed to Address The Risk to Public Health Of Fluoroquinolone-Resistant *Campylobacter*

Campylobacter is estimated to cause the highest number of illnesses of bacterial food-borne pathogens.⁶⁹ A *Campylobacter* infection can lead to serious invasive disease requiring treatment with antibiotics. Fluoroquinolones, such as ciprofloxacin, are the antibiotics of choice for treating *Campylobacter* infections.⁷⁰

However, health care experts have raised concerns that treatment of infections of *Campylobacter* with such antibiotics may be compromised.⁷¹ A study conducted in Minnesota between 1992 and 1998 found that the use of fluoroquinolones, which were first licensed for use in poultry in 1995, has created a reservoir of resistant *C. jejuni*, and that the rate of resistant infections has significantly increased since 1996.⁷² In 1997, 13% of *Campylobacter* isolates received by the CDC via its National Antimicrobial Resistance Monitoring System (NARMS) were ciprofloxacin resistant.⁷³ NARMS data for 1999 has demonstrated that 18% of the human

⁶⁹ Mead, et al., *Food-Related Illness and Death* at 611.

⁷⁰ J. Engberg, et al., *Quinolone and Macrolide Resistance in Campylobacter jejuni and C. coli: Resistance Mechanisms and Trends in Human Isolates*, 7 *Emerging Infectious Diseases* (Jan-Feb. 2001), <<http://www.cdc.gov/ncidod/eid/vol7no1/engberg.htm>> [hereinafter *Quinolone and Macrolide Resistance*].

⁷¹ This concern has recently made the news again. See Philip J. Hilts, *Drug for Poultry Stirs Resistance Concerns*, *New York Times*, p. D7 (Oct. 30, 2001) (reporting that the “agency has estimated that one result of the increased resistance is that 5,000 people a year get campylobacter-caused illness and can no longer be effectively treated with drugs like Cipro”).

⁷² Smith, et al., *Quinolone-resistant Campylobacter* at 1529, 1530.

⁷³ Zirnstein, G., et al. and the NARMS Working Group, *The National Antimicrobial Resistance Monitoring System (NARMS): 1996-1997*, in *Abstracts of the 1998 International Conference on Emerging Infectious Diseases*, p. 138.

Campylobacter infections were due to fluoroquinolone-resistant organisms.⁷⁴

Anti-microbial resistance in *Campylobacter* can prolong illness and comprehensive treatment of patients with bacteremia.⁷⁵ Indeed, one study has indicated that “[a]s *Campylobacter* infections can be serious in immuno-compromised patients, the identified treatment failure raises the concern that fluoroquinolone-resistant strains may increase *Campylobacter*-associated deaths in this group of patients.”⁷⁶

A recent risk assessment developed by the FDA’s Center for Veterinary Medicine estimates that the number of individuals that acquired just fluoroquinolone-resistant infections associated with consuming chicken who subsequently received fluoroquinolone treatment in 1999 was about 9,261 people.⁷⁷ Due to the decreased effectiveness of the drug, it suggested that individuals with resistant infection might experience a longer illness.⁷⁸

The Food and Drug Administration has proposed to withdraw approval of the new animal drug application for use of the fluoroquinolone enrofloxacin (Baytril) in poultry based on its determination that the use of fluoroquinolones causes the development of fluoroquinolone-

⁷⁴ CDC, Division of Bacterial and Mycotic Diseases, Disease Information, *Campylobacter Infections*, Technical Information (Dec. 2000) <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_t.htm>. See also K. Hollinger, et al., *Fluoroquinolone Resistance in Campylobacter from Chicken and Human Health Impact: A Quantitative Risk Assessment Using Data from FoodNet and Other Sources*, 2nd International Conference on Emerging Infectious Diseases, Atlanta, Ga. (July 2000) (finding that of 1.9 million cases of *Campylobacter* infections in the United States in 1998, approximately 5000 people became ill with fluoroquinolone-resistant *Campylobacter* associated with consuming chicken).

⁷⁵ Altekruze, *Campylobacter jejuni - An Emerging Foodborne Pathogen*, at 29.

⁷⁶ *Quinolone and Macrolide Resistance* at 25.

⁷⁷ FDA, Center for Veterinary Medicine, *The Human Health Impact of Fluoroquinolone Resistant Campylobacter Attributed to the Consumption of Chicken* (Oct. 18, 2000, revised Jan. 5, 2001), p. 3-19 [hereinafter *The Human Health Impact of Fluoroquinolone Resistant Campylobacter*].

⁷⁸ Smith, et al., *Quinolone -Resistant Campylobacter*, at p. 1529.

resistant *Campylobacter* in poultry.⁷⁹ We strongly support that action. However, until FDA imposes a ban on the use of this drug, any action USDA takes to reduce pathogens loads of *Campylobacter* on poultry should help to reduce the transfer of resistant pathogens to humans.⁸⁰

B. FSIS Has Legal Authority To Establish A Performance Standard For *Campylobacter* In Poultry

The Poultry Products Inspection Act (PPIA) is premised on a congressional finding that, among other things, “[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, [and] not adulterated”⁸¹ Consistent with this finding, the Act prohibits the sale and transportation of “any poultry products which are capable of use as human food and are adulterated or misbranded.”⁸²

The PPIA 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.”⁸³ Thus, actual contamination of the finished product need not be shown for the agency to find legal “adulteration.”⁸⁴ Under PPIA section 456,

⁷⁹ 65 Fed. Reg. 64,954 (Oct. 31, 2000).

⁸⁰ This is also evidence that the use of antibiotics in food animal production should be restricted.

⁸¹ 21 U.S.C. § 451.

⁸² 21 U.S.C. § 458(a)(2)(A).

⁸³ 21 U.S.C. § 453(g)(4). The definition of adulteration is derived from the Federal Food, Drug and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 342(a)(4).

⁸⁴ See *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914) (interpreting analogue of 21 U.S.C. § 601(m)(1) in Pure Food and Drug Act of 1906 and concluding that if food “may possibly” injure consumers, it is adulterated). See also *Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952) (“the statute is designed to prevent adulterations ‘in their incipiency’ by condemning insanitary conditions which *may* result in contamination”) (citation omitted, emphasis added).

each official establishment slaughtering poultry or processing poultry products otherwise subject to inspection under the Act shall, among other things, “be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce . . . of poultry products which are adulterated.”⁸⁵

Through these statutory provisions, Congress delegated express authority to the Secretary to determine the specific requirements necessary to assure that establishments are producing products that are safe and not adulterated, including the ability to verify that establishments’ facilities are not producing products that are contaminated. 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.”⁸⁶

The Second Circuit has upheld regulations promulgated under similar provisions of the Food, Drug and Cosmetic Act that imposed processing requirements to prevent the growth and spread of pathogens on fish as reasonable “sanitation” measures under the FDCA.⁸⁷ According to the court, failing to control the growth and spread of pathogens in product is an insanitary condition because the “manner of processing can surely give rise to the survival, with attendant

⁸⁵ 21 U.S.C. § 456(a). PPIA section 459 also provides that “[n]o establishment processing poultry or poultry products for commerce or otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter.” 21 U.S.C. § 459.

⁸⁶ *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.”).

⁸⁷ *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 247-48 (2nd Cir. 1977).

toxic effects on humans, of spores which would not have survived under stricter ‘sanitary’ conditions.’’⁸⁸ As a result, the Second Circuit found that the plant was operating under “insanitary conditions because its methods of processing allowed bacteria to survive and to grow on fish, thus rendering the final product potentially injurious to health.”⁸⁹

Like the FDA under the FDCA, USDA has broad regulatory authority under the PPIA to promulgate reasonable regulations to assure that poultry products do not create a health risk to humans. This authority encompasses the ability to establish pathogen reduction standards, including one for *Campylobacter*. Reading the PPIA as a whole, it is clear that Congress intended to delegate broad authority for USDA to institute a comprehensive scheme to address hazards that may arise during processing and to assure that a product is not “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.”⁹⁰

The Fifth Circuit’s recent decision in *Supreme Beef Processors, Inc. v. United States Dep’t of Agriculture* does not prevent FSIS from adopting a performance standard for *Campylobacter* in slaughter plants.⁹¹ In that case, the Fifth Circuit upheld a federal district court decision finding that USDA’s *Salmonella* standard, as applied at meat grinding plants, improperly regulates the *Salmonella* levels of incoming meat, and that *Salmonella* cross-contamination that

⁸⁸ *United States v. Nova Scotia Food Products Corp.*, 568 F.2d at 247.

⁸⁹ *United States v. Nova Scotia Food Products Corp.*, 568 F.2d at 248.

⁹⁰ 21 U.S.C. § 453(g)(4). The validity of a regulation promulgated under a general grant of rulemaking authority will be sustained so long as it is “reasonably related to the purposes of the enabling legislation.” *Mourning v. Family Public Service, Inc.*, 411 U.S. 356, 369 (1973). This is particularly true where, as here, the agency has exercised its scientific judgment. See *Texas Oil and Gas Ass’n v. EPA*, 161 F.3d 923, 938 (5th Cir. 1998).

⁹¹ No. 00-11008 (5th Cir., Dec. 6, 2001).

results from grinding such infected beef cannot be an insanitary condition such that the product is rendered “injurious to health.”

Focusing on the language in section 601(m)(4) of the Federal Meat Inspection Act, 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.”⁹² 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.⁹³ In this case, FSIS could not measure the degree of contaminated product entering the grinding facility compared with the contaminated end-product after grinding. As a result, the panel concluded that the 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 procurement of raw materials.”⁹⁴

While the decision is a setback for USDA in its efforts to regulate pathogens in end products, it 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 (if not earlier). While pathogens may be present at all stages of processing, it is at slaughter where the greatest potential exists for self-contamination and cross-contamination. At slaughter, pathogens are “rendered” onto otherwise sterile meat when the poultry is processed from a live animal to a carcass. As demonstrated earlier, the scald tank and mechanical defeathering are

⁹² Slip opinion at 15.

⁹³ Slip opinion at 15.

⁹⁴ Slip op. at 17.

major sources of contamination during processing. Evisceration is also a point where cross-contamination to previously uncontaminated carcasses occurs.

A *Campylobacter* standard is necessary as a sanitation requirement because of the potential for one *Campylobacter*-infected poultry carcass to infect all the others passing through the same line. Only by establishing process controls and good sanitation measures can establishments assure that they are operating a sanitary slaughter environment and preventing cross-contamination. A pathogen reduction standard is a scientifically valid way to measure the effectiveness of those process and sanitation controls.

Campylobacter infections have been characterized by epidemiological and clinical investigations as the leading cause of bacterial gastroenteritis reported in the United States.⁹⁵ FSIS's own data shows that an estimated 60 to 80 percent of chilled whole birds sampled at processing facilities are contaminated with *Campylobacter*⁹⁶ and that intervention strategies that work to reduce *Salmonella* are not working to achieve similar reductions of *Campylobacter*. Thus, a *Campylobacter*-specific pathogen-reduction standard is needed, not as an indicator of potential contamination by other pathogens but, rather, to assure that plants are implementing effective processes and sanitation measures to reduce the potential for contamination and cross-contamination by this particular pathogen.

Only by adopting a pathogen-reduction standard for *Campylobacter* can FSIS meet the goals and objectives of the PPIA – to protect consumers from poultry products that are

⁹⁵ Altekruze, *Campylobacter jejuni - An Emerging Foodborne Pathogen*, at 28.

⁹⁶ 65 Fed. Reg. at 75,190.

adulterated and assure that poultry products distributed to them are safe and wholesome.⁹⁷

IV. Conclusion

When FSIS promulgated the final HACCP rule, it expressed its commitment “to the development and implementation of future performance standards, as needed, to achieve the FSIS’s public health goal of reducing the incidence of foodborne illness associated with harmful bacteria on raw meat and poultry products.”⁹⁸ It is time for FSIS to follow through on this commitment. *Campylobacter* still continues to contaminate raw poultry products at high levels and consumers, particularly the most vulnerable, continue to experience illness and hospitalizations due to this microorganism. Only a pathogen-reduction performance standard can help the poultry industry and the government identify which pathogen intervention strategies are truly working to help lower levels of *Campylobacter* and assure that high levels of contaminated chicken do not reach consumers.

V. Certification

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

Respectfully submitted,

⁹⁷ 21 U.S.C. §§ 451, 452.

⁹⁸ 61 Fed. Reg. at 38,836.

Karen L. Egbert
Senior Attorney, Food Safety Program

Caroline Smith DeWaal
Director of Food Safety Program

Carol Tucker Foreman, Distinguished
Fellow and Director, Food Policy Institute,
Consumer Federation of America

Mark Silbergeld, Co-Director,
Consumers Union, Washington Office