

**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE**

**CITIZEN PETITION REQUESTING)
ADMINISTRATIVE ACTION TO PREVENT)
AND WARN CONSUMERS ABOUT)
FECAL CONTAMINATION OF MEAT)
AND POULTRY)**

Docket No.: _____

Submitted on August 29, 2001, by:

**Physicians Committee for Responsible Medicine
Mindy S. Kursban, Esq., Staff Counsel
5100 Wisconsin Ave., N.W., Suite 400
Washington, DC 20016
202-686-2210**

Submitted to:

**Thomas J. Billy, Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture**

TABLE OF CONTENTS

INTRODUCTION	1
PETITIONER	2
REQUESTS FOR ADMINISTRATIVE ACTION.....	2
STATEMENT OF FACTS.....	3
I. Foodborne Pathogens and Illness.....	3
A. Background.....	3
B. Major Foodborne Pathogens.....	4
1. <i>E. coli</i> O157:H7.....	4
2. Salmonella.....	5
3. Campylobacter.....	5
4. <i>Listeria Monocytogenes</i>	6
II. Federal Laws and Regulations.....	7
A. Federal Meat Inspection Act.....	7
B. Poultry Products Inspection Act.....	8
C. USDA Regulations and FSIS Directives.....	8
D. Microbiological Testing Programs.....	10
1. Generic <i>E. coli</i> Testing Program.....	10
2. Salmonella Testing Program.....	11
3. Other Mandatory Testing Programs.....	11
a. Salmonella in Ready-to-Eat Products.....	12
b. <i>Listeria Monocytogenes</i> in Ready-to-Eat Products.....	12
c. <i>E. coli</i> O157:H7 in Raw Ground Beef.....	12
ARGUMENT.....	13
I. FSIS Should Declare Feces, Whether Visible or Not, an Adulterant and Regulate Feces as an Adulterant.....	13
A. Feces on Carcasses Are the Primary Avenue of Transmission of Foodborne Pathogens on Meat and Poultry Products.....	13
B. Meat and Poultry Contaminated with Feces Are “Adulterated” under the FMIA and the PPIA.....	16
C. Meat and Poultry Sold Commercially Should Be Free from Fecal Contamination.....	17
D. Feces Should Be Regulated as an Adulterant.....	17

II. FSIS Must Mandate the Application of a Biohazard Warning Label on Meat and Poultry to Prevent Misbranding.	18
III. The Authorized Poultry Inspection Legend Should Be Modified to Exclude the Word “Wholesome”	21
ECONOMIC IMPACT.	22
I. The Economic Cost of Declaring and Regulating Feces as an Adulterant Will Be Outweighed by the Reduction in Costs Associated with Foodborne Illness.	22
II. The Economic Cost of Mandating a Biohazard Warning Label on Meat and Poultry Products Will Be Outweighed by the Reduction in Costs Associated with Foodborne Illness.	23
III. The Economic Cost for Changing the Poultry Inspection Legend Is Minimal.	23
CONCLUSION.	23

INTRODUCTION

Is it reasonable that the chicken sold in grocery stores is likely contaminated with feces? Is it reasonable that if a consumer undercooks a hamburger, her three-year-old could die? Is it reasonable that the consumer, not industry, is responsible for ensuring that meat and poultry are disease-free?

Under current U.S. Department of Agriculture (“USDA”) regulations, the answer to each of these questions is *yes*. Current regulations allow fecally contaminated poultry and meat to be passed at inspection, as long as the feces are not “visible” to the naked eye. Under current regulations, children regularly become severely ill or even die from consuming meat or poultry that was not cooked to precisely the right temperature. Because current USDA regulations are too weak to guarantee that adulterated poultry and meat will not be sold to consumers, USDA has implemented programs that place the burden squarely on consumers to kill foodborne pathogens on their fecally contaminated meat and poultry—or suffer the potentially deadly consequences.

Despite having laws in place since 1906 intended to ensure a wholesome meat supply, foodborne illness has become a major public health epidemic in this country. The Centers for Disease Control and Prevention (“CDC”), which reports only what it believes to be a fraction of foodborne disease incidents, estimates that 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths are caused by foodborne pathogens annually. That is 200,000 Americans are sickened by a foodborne disease every day, of whom 900 are hospitalized and 14 die. The vast majority of these foodborne illnesses can be traced to the production, processing, or consumption of items of animal origin—meat, poultry, fish, dairy products, and eggs.¹

However, it is not the actual consumption of meat and poultry² that causes foodborne illness, although such consumption increases the risk of heart disease, hypertension, diabetes, cancer, and other health conditions. Rather, it is the presence of feces on meat and poultry that causes humans to ingest foodborne pathogens and, therefore, get sick from eating these products. Despite the “official” USDA policy of zero tolerance for fecal contamination, the extraordinary rates of foodborne illness in this country are directly caused by eating poultry and meat contaminated with feces even though they passed inspection by USDA’s Food Safety and Inspection Service (“FSIS”).

FSIS oversees the inspection of all poultry and meat products. FSIS also implements the zero-tolerance policy for fecal contamination—albeit only for visible fecal contamination—through

¹ For instance, poultry and meat carcasses can become contaminated during slaughter by contact with small amounts of intestinal contents; fresh fruits and vegetables can be contaminated if grown in contaminated manure as fertilizer or are washed or irrigated with water contaminated with infected animal manure; some types of salmonella can infect a hen’s ovary so the internal contents of a normal-looking egg can be contaminated even before the shell is formed; microbes can be transferred from one piece of contaminated food to another via knives, cutting boards, or other utensils; fully cooked meat or poultry on which all pathogens have been killed can become recontaminated if it touches other raw meat or poultry or drippings from raw meat poultry that contains pathogens. CDC/Division of Bacterial and Mycotic Diseases (“DBMD”), Foodborne Infections General Information, *How does food become contaminated?*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#howcontaminated>.

² Although all foods of animal origin are likely to carry foodborne pathogens, this Petition is limited to regulations governing meat and poultry and, therefore, will not discuss fish, dairy products, or eggs any further.

directives that authorize spraying, washing, trimming, or steam-vacuuming carcasses to remove visible feces, checking quality control data, and infrequent fecal spot-checks for process control. Yet, the prevalence of foodborne illness in this country caused by eating fecally contaminated meat and poultry remains staggeringly high, providing clear evidence that current inspection methods and regulations are insufficient and misdirected.

PETITIONER

Petitioner Physicians Committee for Responsible Medicine (“PCRM”) is a national, nonprofit, health advocacy organization based in Washington, D.C., comprised of approximately 5,000 physician and approximately 100,000 layperson members. PCRM teaches consumers, educators, and policy-makers about using a plant-based diet as a tool for preventive medicine and maintaining good health. PCRM advocates strengthening the reliance on preventive measures in the production and slaughter processes for animals used as food to eradicate foodborne illness caused from eating fecally contaminated poultry and meat.

REQUESTS FOR ADMINISTRATIVE ACTION

The Federal Meat Inspection Act³ (“FMIA”) and the Poultry Products Inspection Act⁴ (“PPIA”) direct the Secretary of Agriculture to inspect all meat and poultry. If, upon such inspection, the meat or poultry is found to be unadulterated, the product can pass inspection and be labeled as such, indicating that the product is wholesome and safe to eat.⁵ If the meat or poultry is adulterated, it must be condemned to keep it from reaching consumers.⁶ Inconsistent with this mandate, USDA regularly passes at inspection poultry and meat that is fecally contaminated, consequently conveying to consumers a false promise of wholesomeness.

In order to prevent this ongoing violation of the law and to prevent the continued release of fecally contaminated poultry and meat from slaughterhouses and processing plants, PCRM, pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(e), and 7 C.F.R. § 1.28, petitions FSIS to take following actions:

1. Declare feces an adulterant and regulate feces as an adulterant.
2. Amend Title 9 of the Code of Federal Regulations to mandate that, in addition to the inspection legend and safe-handling instructions, all meat and poultry products carry a biohazard warning label stating: “Biohazard: This product may be contaminated with feces and, therefore, hazardous to your health.”
3. Amend Title 9 of the Code of Federal Regulations Section 381.123 to mandate a poultry inspection legend that does not include the word “wholesome” or any other descriptive word that implies that poultry products are safe to eat.

³ 21 U.S.C. § 601, et seq. (1906).

⁴ 21 U.S.C. § 451, et seq. (1957).

⁵ 21 U.S.C. §§ 451, 604.

⁶ Id.

STATEMENT OF FACTS

I. Foodborne Pathogens and Illness

A. Background

CDC estimates that 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths are caused by foodborne pathogens annually.⁷ Known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths annually.⁸ The major foodborne pathogens in the United States are *Escherichia coli* (“*E. coli*”) 0157:H7, salmonella, *Campylobacter jejuni* (“campylobacter”), and *Listeria monocytogenes* (“*L. monocytogenes*”). CDC estimates that each year there are approximately 73,000 *E. coli* 0157:H7 infections and 60 related deaths; 1.4 million salmonella infections and 1,000 related deaths; 2.4 million campylobacter infections and 124 related deaths; and 2,500 *L. monocytogenes* infections and 500 related deaths.⁹ Because many ill persons do not seek medical attention and, of those who do, many are not tested, many cases of foodborne illness go undiagnosed. For example, CDC estimates that 38 cases of salmonellosis actually occur for every case that is diagnosed and reported to public health authorities.¹⁰

USDA’s Economic Research Service (“ERS”) estimates that the economic costs incurred for these major bacterial pathogens alone—including medical costs, productivity losses from missed work, and an estimate of the value of premature deaths—amount to at least \$6.9 billion annually.¹¹

Animal products such as red meat, poultry, eggs, seafood, and dairy products are the foods most likely to cause human illness.¹² Further, because feces are the vehicle for transmission of pathogens to humans who consume animal flesh,¹³ the true cause of foodborne illness related to the consumption of meat or poultry is the presence of feces infected with pathogenic bacteria on that meat or poultry. Thus,

⁷ CDC/DBMD, Foodborne Infections Technical Information, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_t.htm>.

⁸ *Id.*

⁹ CDC/DBMD reports, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm>, <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm>, <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm>, <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm>.

¹⁰ CDC/DBMD, Foodborne Diseases General Information, *How are foodborne diseases diagnosed?*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm>.

¹¹ USDA/ERS, Food Safety, available at <<http://www.ers.usda.gov/Emphases/SafeFood/>>.

¹² USDA/ERS, Bacterial Foodborne Disease: Medical Costs and Productivity Losses. Agricultural Economic Report No. 741 (August 1996); CDC/DBMD, Foodborne Infections General Information, *What foods are most associated with foodborne illness?*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#riskiestfoods>; See also Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. 6774 (proposed February 3, 1995).

¹³ CDC/DBMD, Salmonellosis General Information, *How do people catch Salmonella?*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm> and Campylobacter Infections General Information, *How does food or water get contaminated with Campylobacter?*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm>; FSIS Backgrounder, *Escherichia coli Update: E. Coli 0157:H7*, (January 1993) at 1.

if meat or poultry is contaminated with pathogenic bacteria, it is most likely also contaminated with feces.

B. Major Foodborne Pathogens

1. *E. coli* O157:H7¹⁴

The species *E. coli* is comprised of hundreds of strains of bacteria that normally inhabit the intestines and colons of warm-blooded animals, including humans. Although most strains of *E. coli* are harmless, *E. coli* O157:H7 is a mutant strain found specifically in the intestinal tracts of cattle.¹⁵ *E. coli* O157:H7 produces a powerful toxin and can cause severe illness, ranging from mild diarrhea to severe bloody diarrhea, hemolytic uremic syndrome (HUS),¹⁶ and death.¹⁷ The number of *E. coli* O157:H7 organisms required to cause sickness is suspected to be very small.

The muscle (“meat”) of cattle does not carry the pathogen. Rather, meat becomes contaminated during slaughter when it comes into contact with the feces of infected cattle. *E. coli* O157:H7 was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea traced to contaminated hamburgers. Since then, most infections have come from eating ground beef, which is made from the meat of up to 100 different animals. Thus, if one of those animals is contaminated, the *E. coli* O157:H7 bacteria are thoroughly mixed into the beef when it is ground, and the whole batch becomes contaminated. Illness has also been reported from eating other species, such as pigs, as well as other cuts of meat.¹⁸

As current inspection standards cannot ensure a meat supply free from contamination of *E. coli* O157:H7, consumers are advised through FSIS programs such as *Fight Bac!* and the *Thermy Campaign* to cook meat to a minimum temperature of 160°F to kill the pathogen.

¹⁴ The information in this section is taken from the information provided by CDC on *E. coli* O157:H7, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm>.

¹⁵ *E. coli* O157:H7 has been found to colonize the ceca (the large pouch forming the beginning of the large intestine) of chickens and has been isolated from retail poultry in the United States, FSIS has never found *E. coli* O157:H7 in raw or ready-to-eat poultry samples. Performance Standards for the Production of Processed Meat and Poultry Products, 66 Fed. Reg. 12,590 (proposed February 27, 2001).

¹⁶ HUS is a severe, life-threatening disease characterized by the destruction of red blood cells, kidney failure, and neurological complications such as seizures and strokes. HUS, once considered a rare disease, is now the leading cause of renal failure in children. The Center for Public Integrity, *Safety Last: The Politics of E. coli and Other Food-Borne Killers*, 1998, at 13.

¹⁷ CDC Editorial Note. Preliminary Report: Foodborne Outbreak of *Escherichia coli* O157:H7 Infections From Hamburgers-Western United States. JAMA 1993;269:1089.

¹⁸ On June 24, 2001 and July 31, 2001, FSIS announced a recall of ground pork products because of positive tests for *E. coli* O157:H7. USDA/FSIS, *Meat and Poultry Product Recalls: News Releases and Information for Consumers*, available at <<http://www.fsis.usda.gov/OA/news/xrecalls.htm>>; Policy on Beef Products Contaminated With *Escherichia Coli* O157:H7, 64 Fed. Reg. 2803-01 (January 19, 1999) (“The public health risk presented by beef products contaminated by *E. coli* O157:H7 is not limited, however, to raw ground beef products.”).

2. Salmonella¹⁹

Salmonella is a genus of 2,300 serotypes of bacteria, most of which can cause human disease. Although there are many different kinds of salmonella bacteria, *Salmonella typhimurium* and *Salmonella enteritis* are the most common types causing illness in the United States. Most persons infected with salmonella develop diarrhea, fever, and abdominal cramps 12 to 72 hours after infection, and are ill from four to seven days. Although most people suffering from salmonellosis recover without treatment, for others, the diarrhea may be so severe that hospitalization is required. In these patients, the salmonella infection may spread from the intestines to the bloodstream, and then to other body sites, and can cause death unless the person receives prompt treatment with antibiotics.

Foods contaminated with salmonella are usually of animal origin, such as raw poultry, beef, and pork, though it is most widely associated with raw poultry.²⁰ The bacteria live in the intestinal tracts of infected animals and are usually transmitted to humans through eating food contaminated with animal feces. Pathogenic salmonella bacteria may not cause symptoms in animals but can still make people sick.

Salmonellosis is the costliest foodborne illness in the United States. ERS estimates that the annual economic costs due to foodborne salmonella infections are \$2.4 billion,²¹ and CDC has estimated that 95 percent of salmonellosis are due to contaminated food products. As few as 15 to 20 salmonella bacteria can cause illness, depending on the strain and the age and health of the individual.²² Moreover, salmonella bacteria multiply quickly if the food product is not kept refrigerated at the proper temperature.

As with *E. coli* 0157:H7, meat and poultry contaminated with salmonella look and smell normal. Consequently, because current inspection standards do not ensure a poultry and meat supply free from salmonella contamination, consumers are advised to “thoroughly” cook their poultry and meat to kill the pathogen.

3. Campylobacter²³

The campylobacter genus is a group of bacteria that can cause disease in humans. Most cases of campylobacteriosis are caused by one species, *Campylobacter jejuni*, but about 1 percent of human campylobacter cases are caused by other species (all campylobacter bacteria will hereinafter be collectively referred to simply as “campylobacter”). Campylobacter grow best at the body temperature of birds, who carry the bacteria in their intestinal tracts without becoming ill. CDC notes that many

¹⁹ The information in this section is taken from the information provided by CDC on salmonella, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm>, unless otherwise noted.

²⁰ Performance Standards for On-line Antimicrobial Reprocessing of Pre-Chill Poultry Carcasses, 65 Fed. Reg. 75,187-02 (proposed December 1, 2000).

²¹ USDA/ERS, *Economics of Foodborne Disease—Salmonella*, available at <<http://www.ers.usda.gov/briefing/FoodborneDisease/Salmonella/index.htm>>.

²² U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition, *Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Salmonella ssp.* (commonly known as the “Bad Bug Book”).

²³ The information in this section is taken from the information provided by CDC on campylobacter available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm>, unless otherwise noted.

chicken flocks are “silently” infected with campylobacter; that is, the chickens are infected with the organism but show no signs of illness.

Campylobacter can be easily spread from bird to bird through contact with infected feces. Thus, when an infected bird is slaughtered, campylobacter in the bird’s feces can then be transferred to the meat of that infected bird, as well as other uninfected birds, through contact with the feces. As a result, anywhere from 50 to 80 percent of the raw chicken in the U.S. market is contaminated with campylobacter.²⁴ Not surprisingly, most cases of campylobacteriosis are associated with handling raw poultry or eating raw or undercooked poultry meat. Even one drop of fluid from contaminated chicken meat can carry enough campylobacter to infect a person.

Campylobacter infection affects more than 2 million persons, or 1 percent of the population, every year. Most people who become ill with campylobacteriosis experience diarrhea, cramping, abdominal pain, and fever within two to five days after exposure. The illness typically lasts one week. Although for some persons, infection with campylobacter causes no symptoms, when campylobacter has spread to the bloodstream, it causes a serious life-threatening infection. Campylobacter infection also can cause Guillain-Barré Syndrome, a disease that affects the nerves of the body leading to paralysis,²⁵ and death.²⁶

As with *E. coli* 0157:H7 and salmonella, current industry practices and inspection regulations fail to eliminate, or even significantly reduce, campylobacter from the food supply. Thus, the government places the burden on consumers to kill the pathogen on meat and poultry.

4. *Listeria Monocytogenes*²⁷

Listeria monocytogenes (“*L. monocytogenes*”), the toxic species of listeria, is a bacterium that has only recently been recognized as a foodborne pathogen, and is now considered one of the most dangerous pathogens in our food supply. Most cases of listeriosis involve foodborne transmission.

Although listeriosis from contaminated food is less common than infections from other foodborne pathogens, its consequences are far more severe. A person with listeriosis experiences fever, muscle aches, and sometimes gastrointestinal symptoms such as nausea or diarrhea. If infection spreads to the nervous system, symptoms such as headache, stiff neck, confusion, loss of balance, or convulsions can occur. Infected pregnant women may experience only a mild, flu-like illness; however, infections during pregnancy can lead to premature delivery, infection of the newborn, or even stillbirth. The most common manifestation of listeriosis is meningitis, which has symptoms of high fever, severe headache, neck stiffness, and nausea.²⁸ Of the approximately 2,500 persons who become ill with listeriosis each

²⁴ 65 Fed. Reg. 75,187-02, *supra* note 20.

²⁵ It is estimated that approximately 1 in every 1,000 reported campylobacteriosis cases leads to Guillain-Barré Syndrome, and as many as 40 percent of Guillain-Barré Syndrome cases in this country may be triggered by campylobacteriosis.

²⁶ Approximately 500 persons with campylobacter infections die each year.

²⁷ The information in this section is taken from the information provided by CDC on listeriosis, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm>, or from “About-Listeria” available at <<http://www.about-listeria.com>>, unless otherwise noted.

²⁸ FSIS Backgrounder, *FSIS Strategies for Addressing Listeria Monocytogenes* (February 1999).

year, 20 percent die. Moreover, 92 percent of listeriosis cases require hospitalization—the highest among foodborne pathogens.

Livestock and poultry can carry *L. monocytogenes* without appearing ill and can spread the pathogen through their feces. Thus, raw meat contaminated with feces from an animal harboring *L. monocytogenes* could infect a person who consumes that meat.

L. monocytogenes is unique in its growth capabilities, having a growth range in temperatures between 25°F to 98°F. Highly prevalent in raw meat, researchers have detected the pathogen in up to 77 percent of ground beef and 95 percent of ground pork.²⁹ Although occurring less frequently than in raw products, *L. monocytogenes* is also commonly found in meat and poultry products considered “ready-to-eat,” which are usually consumed without further cooking. Limited data suggest that *L. monocytogenes* may be killed by pasteurization and by the heating methods used to prepare ready-to-eat processed meats, but evidence supporting this belief is not conclusive.³⁰

As with the other pathogenic bacteria discussed herein, current inspection regulations fail to adequately prevent contamination of meat and poultry products with *L. monocytogenes*.

II. Federal Laws and Regulations

A. Federal Meat Inspection Act

In 1906, Congress authorized and mandated USDA to conduct inspections of “livestock” animals (cows, pigs, goats, sheep, and horses) used for food before (ante-mortem) and after (post-mortem) slaughter and during the processing operation to prevent the distribution and sale of meat that was unwholesome, adulterated, unhealthful, and not properly marked, labeled, and packaged.³¹

Under this inspection system, Congress mandated that USDA shall ensure that only unadulterated carcasses be approved for further distribution to consumers. If meat is found to be unadulterated, USDA is required to affix an inspection legend indicating that the meat has been inspected by USDA, passed the inspection, and is safe to eat.³² The mandatory inspection legend for all unadulterated meat products reads: “Inspected and passed.”³³

All adulterated carcasses are prohibited from being distributed to consumers.³⁴ They must be marked as “Inspected and condemned” and are prohibited from use as food.³⁵ The underlying principle, then,

²⁹ Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, Task Force Report No. 122 (1994), at 45.

³⁰ Council for Agricultural Science and Technology, *Johne’s Disease in Cattle*, Issue Paper No. 17 (May 2001).

³¹ 21 U.S.C. §§ 601.

³² 21 U.S.C. § 601(n)(12).

³³ 21 U.S.C. § 604(a).

³⁴ Id.

³⁵ Id.

of the FMIA—and upon which all the other provisions rely—is that adulterated meat is unsafe for consumers to eat and, thus, cannot be passed at inspection by USDA for sale to the public.³⁶

Under the FMIA, meat is adulterated, in relevant part:

“if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health” or

“if it consists in whole or part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.”³⁷

Further, the FMIA prohibits the misbranding of meat. Meat is misbranded, in relevant part, “if its labeling is false or misleading in any particular” or “if it fails to bear...the inspection legend and...such other information as the USDA may require...to assure that it will not have false or misleading labeling.”³⁸

B. Poultry Products Inspection Act

Like the FMIA, Congress enacted the PPIA to protect the “health and welfare of consumers...by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”³⁹ The PPIA is similar in most respects to the FMIA except that it governs poultry (chickens, turkeys, ducks, geese, and guineas). Thus, the PPIA requires ante-mortem and post-mortem inspection,⁴⁰ defines “adulterated” identically as it is defined in the FMIA,⁴¹ and prohibits the misbranding of poultry, again applying the same definition of “misbranding” as used in the FMIA.⁴² Also, like the FMIA, the basic principle underlying the PPIA is that adulterated poultry is unsafe for consumers to eat and, thus, cannot be passed at inspection by USDA for sale to the public.

While the PPIA also mandates application of an inspection legend to all unadulterated poultry indicating that it has passed inspection as required by law, it does not specify the exact language that must be included on the legend, leaving discretion of this matter to USDA.⁴³

C. USDA Regulations and FSIS Directives

USDA regulations implementing the FMIA and PPIA are found in Title 9 of the Code of Federal Regulations at Chapter III, 9 C.F.R. pt. 300, et. seq. USDA has delegated the responsibility for en-

³⁶ See 21 U.S.C. § 608.

³⁷ 21 U.S.C. §§ 601(m)(1), (m)(3).

³⁸ 21 U.S.C. §§ 601(n)(1), (n)(12).

³⁹ 21 U.S.C. § 451.

⁴⁰ 21 U.S.C. § 455.

⁴¹ 21 U.S.C. §§ 453(g)(1), (g)(3).

⁴² 21 U.S.C. § 453(h).

⁴³ 21 U.S.C. §§ 453(m), 457(a).

forcing the FMIA and PPIA to the FSIS.⁴⁴ To implement and enforce the inspection laws, FSIS developed directives that provide detailed instructions for FSIS inspectors.

Pursuant to the authority granted under the FMIA, USDA permits the use of several inspection legends for meat, including “Inspected and passed,” “U.S. Inspected and Passed,” or “U.S. Inspected and Passed by Department of Agriculture,” all of which contain the required phrase, “inspected and passed.”⁴⁵ For poultry, USDA authorizes only one inspection legend: “Inspected for wholesomeness by U.S. Department of Agriculture.”⁴⁶ All poultry that has passed inspection must bear the “Inspected for wholesomeness” label.⁴⁷ Each livestock or poultry carcass that is found on final inspection to be “unsound, unhealthful, unwholesome, or otherwise adulterated” must be marked as “U.S. Inspected and Condemned.”⁴⁸

In addition to the official inspection legend, USDA requires that safe-handling labels be placed on all raw meat and poultry products.⁴⁹ The safe-handling label advises that the meat or poultry product was prepared from inspected-and-passed meat or poultry. Then, in contradiction to this implied assurance of wholesomeness, the safe-handling label advises that “[s]ome food products may contain bacteria that could cause illness.”⁵⁰ It then advises the consumer on handling and cooking procedures to prevent illness associated with foodborne pathogens.⁵¹

FSIS has been directed to enforce a zero-tolerance standard for visible fecal material. This standard is reflected in USDA regulations, which require, *inter alia*, that establishments handle livestock carcasses and carcass parts to prevent contamination with fecal material and promptly remove contamination if it occurs,⁵² and that establishments prevent poultry carcasses contaminated with visible fecal material from entering the “chilling tank.”⁵³ When inspection program personnel observe feces at post-mortem livestock inspection or thereafter under the FMIA or when poultry carcasses are about to enter the chilling tank or thereafter (i.e., at any point after the final pre-chiller wash) under the PPIA, they are supposed to condemn the affected product unless the visible feces are removed by reprocessing.⁵⁴ Reprocessing includes trimming, vacuuming, or washing a carcass where it has been contaminated.⁵⁵

⁴⁴ 9 C.F.R. § 300.

⁴⁵ 9 C.F.R. § 301.2.

⁴⁶ 9 C.F.R. §§ 381.1, 381.96.

⁴⁷ 9 C.F.R. § 381.123.

⁴⁸ 9 C.F.R. §§ 310.5, 381.1.

⁴⁹ 9 C.F.R. §§ 317.2(l); 381.125(b)(1)(i).

⁵⁰ Id.

⁵¹ Id.

⁵² 9 C.F.R. § 310.18.

⁵³ 9 C.F.R. § 381.65(e). A “chilling tank” is a large vat of water that serves as a common bath for all poultry carcasses after inspection.

⁵⁴ See Notice on Complying with Food Safety Standards under the HACCP System Regulations: Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material, 62 Fed. Reg. 63,254-01 (November 28, 1997); Poultry Post-Mortem Inspection and Reinspection—Enforcing the Zero Tolerance for Visible Fecal Material, FSIS Directive 6150.1 (June 19, 1998).

⁵⁵ 9 C.F.R. §§ 310.18, 381.91(b)(1); FSIS Directive 6150.1, supra note 54; Livestock Post-Mortem Inspection Activities—Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk, FSIS Directive 6420.1 (December 17, 1998).

In 1996, FSIS began implementation of its Pathogen Reduction and Hazard Analysis and Critical Control Point Systems (“HACCP”).⁵⁶ HACCP is intended to identify hazards that may arise at “critical points” in the production process of meat and poultry and devise measures to minimize the risks associated with these hazards. Under HACCP, (1) all meat and poultry plants must develop and implement a system of preventive controls, (2) slaughter plants and plants producing raw ground products must meet established pathogen reduction performance standards for salmonella, verified through microbial spot-checking by FSIS, (3) meat and poultry plants must develop and implement written standard operating procedures for sanitation, and (4) meat and poultry slaughter plants must conduct a microbial spot-check for generic *E. coli*.⁵⁷ HACCP’s *E. coli* and salmonella spot-checking systems are meant to verify whether the plant’s systems are working as intended to prevent fecal contamination.⁵⁸

A plant is deemed to be operating in compliance with HACCP if it meets the established performance standards (pre-HACCP prevalence levels of the particular pathogen). Test results that indicate the presence of what the FSIS has deemed to be unacceptable levels of the pathogen are an indication that the establishment needs to review process controls and take corrective actions as determined by the plant.

D. Microbiological Testing Programs

1. Generic *E. coli* Testing Program⁵⁹

Slaughter and process plants that produce poultry and meat are required to meet pathogen reduction performance standards for generic *E. coli* (not *E. coli* 0157:H7) as a process control indicator for fecal contamination. The plant operates the generic *E. coli* testing program by testing carcasses for the non-pathogenic bacteria on a per volume basis. That is, the plant is only required to test 1 out of every 22,000 chicken carcasses, 1 out of every 300 cattle carcasses, and one 1 of every 1,000 pig carcasses. The plant collects the bacteria samples, tests the samples, and records the results. The data relating to the testing program are maintained by the plant.

Thereafter, to evaluate whether the plant is complying with the generic *E. coli* testing program procedures, FSIS inspectors spot-check the test results as recorded by the industry. Test results that do not meet the performance standard for generic *E. coli* indicate an establishment may not be maintaining process controls sufficient to minimize fecal contamination. In such case, the FSIS inspector should complete a non-compliance record and “take further action as appropriate to ensure that applicable provisions of the law are met.” FSIS explicitly states that generic *E. coli* performance standards are not

⁵⁶ Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems (“hereinafter referred to as “HACCP Final Rule”), 61 Fed. Reg. 38,806-01 (July 25, 1996) codified at 9 C.F.R. § 417. HAACP has been nicknamed by many FSIS inspectors as “Have a Cup of Coffee and Pray.” Safety Last, supra note 16, at 13.

⁵⁷ Generic *E. coli* is a common bacterium that does not cause disease; rather, it indicates the presence of feces. FSIS, “Key Facts: HACCP Final Rule,” July 1996.

⁵⁸ HACCP Final Rule, supra note 56; See also 9 C.F.R. §§ 310.25; 381.94.

⁵⁹ All information provided in this section can be found at 9 C.F.R. §§ 310.25(a), 381.94(a), and Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations, FSIS Directive 5000.1 (November 21, 1997), at Part Four, paragraph IV.

regulatory standards; thus, FSIS does not use the test results to determine whether products are adulterated or whether they can be sold to the public.

2. Salmonella Testing Program⁶⁰

The pathogen reduction performance standards for salmonella apply to livestock and poultry slaughterhouses and to plants that produce raw ground poultry and meat products. The performance standards are based on industry averages, rather than an estimate of how much salmonella it takes to make someone sick. Separate performance standards apply to each species slaughtered and the class of the product produced. The performance standards are expressed in terms of the maximum number of positive samples that are allowed per sample set (a “test” consists of a full sample set). Sample sets are statistically determined and range from 51 samples for broiler chickens to 82 samples for steers and heifers. For example, in steers and heifers, 1 out of 82 samples is permitted to be positive. For broiler chickens, 12 out of 51 samples are permitted to be positive. Tests are either positive or negative—the results are not expressed in terms of number of organisms found in a sample.

In contrast to the generic *E. coli* spot-check system, in which industry collects and tests samples based on how many animals it slaughters, FSIS inspectors collect the samples and perform the tests to detect the presence of salmonella. Further, the frequency of the salmonella checks is not based on the number of animals slaughtered; rather the frequency of testing is done randomly at the discretion of FSIS, based on an establishment’s performance history.

When the first set of test results are non-compliant with the salmonella performance standard, the FSIS inspector is to complete a non-compliance record.⁶¹ The plant is then put in line for a second salmonella test, which only has to be performed sometime during the ensuing two months.⁶² When repeat violations occur, the inspector may deem the non-compliance a failure to maintain an adequate HACCP plan or order inspection services withheld.⁶³ A positive result for salmonella in raw product generally does not result in an adulteration determination.⁶⁴

3. Other Mandatory Testing Programs

In addition to the microbial testing spot-checks for process control verification, FSIS also mandates other testing programs meant to prevent the distribution of adulterated products.⁶⁵

⁶⁰ All information provided in this section can be found at 9 C.F.R. § 310.25(b) and § 381.94(b)(1), unless otherwise noted.

⁶¹ Enforcement for the Salmonella Performance Standards, FSIS Directive 10,011.1 (September 9, 1998).

⁶² Id.

⁶³ See also FSIS Directive 5000.1, supra note 59, at Part I.

⁶⁴ 66 Fed. Reg. 12,590, supra note 15.

⁶⁵ FSIS has indicated its intent to propose more pathogen reduction performance standards to eventually cover every processing category. Irradiation of Meat Food Products, 64 Fed. Reg. 72,150-01, 72,153 (December 23, 1999).

a. Salmonella in Ready-to-Eat Products

FSIS has a zero-tolerance policy for salmonella in ready-to-eat products. Under FSIS's Microbiology Monitoring Program, ready-to-eat poultry and meat products are subject to random sampling and testing requirements for the presence of salmonella.⁶⁶ The presence of salmonella in a ready-to-eat meat or poultry product renders it adulterated and subject to a voluntary recall.⁶⁷

b. *L. monocytogenes* in Ready-to-Eat Products

FSIS has a zero-tolerance policy for *L. monocytogenes* in ready-to-eat products. Under FSIS's Microbiology Monitoring Program, ready-to-eat meat and poultry products are subject to random sampling and testing requirements for the presence of *L. monocytogenes*.⁶⁸ Further, processing plants must set forth in their HACCP plans how they will control for *L. monocytogenes* in ready-to-eat meat and poultry products.⁶⁹ Any amount of *L. monocytogenes* found in a ready-to-eat meat or poultry product renders it adulterated and subject to a voluntary recall,⁷⁰ and is evidence that a HACCP plan may be inadequate and, therefore, should be reassessed.⁷¹ Currently under this program, FSIS inspectors annually test only about 7,000 samples of domestic and imported products for the presence of *L. monocytogenes*.⁷²

c. *E. coli* 0157:H7 in Raw Ground Beef⁷³

In 1994, USDA declared that ground beef contaminated with *E. coli* O157:H7 is adulterated under the FMIA, creating accountability for the presence of this pathogen in ground beef.⁷⁴ Tied to this new definition of *E. coli* 0157:H7 is a limited microbiological testing program for the pathogen in raw ground beef conducted either by FSIS or the regulated establishment.⁷⁵ If the establishment conducts its own in-house testing, which most do, FSIS is responsible for verifying that the sampling program is being implemented. As long as the establishment uses "validated pathogen reduction interventions," which all are required to do under HACCP, the plant is not required to test for *E. coli* 0157:H7 on any predetermined frequency, just "routinely."

⁶⁶ Microbiological Monitoring Program: Sampling, Testing Procedures and Actions for *Listeria Monocytogenes* and *Salmonella*, FSIS Directive 10,240.1 (June 2, 1997).

⁶⁷ Performance Standards for the Production of Processed Meat and Poultry Products, 66 Fed. Reg. 12,589 (proposed February 27, 2001).

⁶⁸ FSIS Directive 10,240.1, supra note 66.

⁶⁹ *Listeria monocytogenes*, Contamination of Ready-to-Eat Products, 64 Fed. Reg. 28,351 (May 26, 1999).

⁷⁰ Id.

⁷¹ FSIS Directive 5000.1, supra note 59, at Part I, paragraph III.A.

⁷² 66 Fed. Reg. 12,589, supra note 67.

⁷³ All information provided in this section can be found at Microbiological Testing Program for *Escherichia coli* 1057:H7 in Raw Ground Beef, FSIS Directive 10,010.1 (February 1, 1998), unless otherwise noted.

⁷⁴ FSIS Notice 50-94, Microbiological Testing Program for *Escherichia coli* 0157:H7 in Raw Ground Beef (December 23, 1994); See also Texas Food Industry Association v. Espy, 870 F.Supp. 143 (W.D. Texas 1994).

⁷⁵ "Establishments" subject to this regulation include plants that grind beef and retail outlets that regularly grind beef.

If a sample tests positive for *E. coli* 0157:H7, the sampled lot⁷⁶ is supposed to be condemned unless it is reprocessed to remove the adulterant and follow-up testing is conducted. Further, if a sample is confirmed positive, all products from the shift represented by the positive sample are subject to a voluntary recall. However, FSIS does not have the authority to mandate a recall and even when industry institutes a voluntary recall, a majority of the contaminated product is never recovered.⁷⁷ This is due, in part, to the fact that most recalls are not even issued until at least five to six days after the product was shipped, and have even been issued seven months after the date of shipment.⁷⁸

ARGUMENT

The poultry and meat inspection system costs American taxpayers approximately \$700 million annually.⁷⁹ FSIS advises the public that this inspection system, with its various zero-tolerance policies and microbial testing programs, serves as satisfactory means for preventing foodborne illness. While on paper it appears that FSIS has the structure for an effective food safety program, the facts belie this conclusion. The current inspection system does not provide adequate protection against foodborne illness.

Stringent and proactive rules, policies, and enforcement measures must be taken by FSIS to prevent the continued fecal contamination of poultry and meat. Further, until such time as foodborne illness caused by eating fecally contaminated poultry and meat is stopped, consumers must be vigilantly warned, and no longer misled, about the inherent risk involved with consuming meat or poultry products that have passed inspection.

I. FSIS Should Declare Feces, Whether Visible or Not, an Adulterant and Regulate Feces as an Adulterant.

A. Feces on Carcasses Are the Primary Avenue of Transmission of Foodborne Pathogens on Meat and Poultry Products.

Feces are the major source of bacterial contamination in livestock and poultry slaughterhouses,⁸⁰ and the consumption of meat and poultry contaminated with feces is the primary vehicle for transmitting foodborne pathogens to humans.⁸¹ One-third of U.S. cattle harbor *E. coli* 0157:H7.⁸² *Consumer Reports*

⁷⁶ A sampled lot is all raw ground-beef products produced between performance of complete cleaning and sanitization procedures for all equipment used in handling or processing a raw ground-beef product.

⁷⁷ *Safety Last*, supra note 16, at 12.

⁷⁸ USDA/FSIS, *Meat and Poultry Product Recalls: News Releases and Information for Consumers*, supra note 18.

⁷⁹ Statement of Thomas J. Billy, FSIS Administrator, before the Senate Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies, April 26, 2001.

⁸⁰ Statement by Mark Rasmussen, microbiologist with Agricultural Research Service at the National Animal Disease Center in Ames, Iowa, available at <<http://www.ars.usda.gov/is/pr/1998/980317.htm>>.

⁸¹ 62 Fed. Reg. 63,254, supra note 54; See also Poultry Inspection: Revision of Finished Product Standards With Respect to Fecal Contamination, 62 Fed. Reg. 5139, 5140 (February 4, 1997) (“Fecal contamination is a food safety hazard because of its direct link to microbial contamination and foodborne illness.”)

⁸² Charlotte Schubert, *Busting the Gut Busters: Virulent E. coli are revealing some weaknesses*, *Science News*, August 4, 2001;160:74-6.

magazine reported that virtually every chicken on the market is contaminated with feces.⁸³ Preventing poultry and meat carcasses contaminated with feces, whether visible or not, from leaving the slaughterhouse is integral to efforts to eradicate foodborne illness.⁸⁴ Yet, current policy regarding fecal contamination on meat and poultry only addresses feces that are “visible” to the naked eye, permits processes that contribute to the spread of fecal contamination, and authorizes plants to reprocess contaminated carcasses with methods that do not provide adequate safeguards to the consumer.

If neither the plant workers nor the inspectors see the feces in the course of performing their job, a carcass contaminated with feces and, therefore, potentially infected with pathogenic bacteria and other health hazards, passes through the plant for sale to consumers.⁸⁵ Permissible transport, handling, slaughter, and process methods under current large-scale food-animal production make it likely that many animals will be contaminated and cross-contaminated with feces, and that “visible” feces will not be seen on a carcass or, if it is seen, that it will not be removed completely.

To begin with, pathogenic bacteria are transferred from infected animals to uninfected ones as a result of mass transportation of animals to slaughterhouses and their maintenance in communal holding pens not amenable to thorough sanitizing. Thus, feces enter the slaughterhouse via an animal who has been soiled with feces during transport, which, in turn, results in the contamination of other animals.

Slaughter production lines are fertile grounds for the spread of hazardous bacteria. Poultry plants collectively slaughter 21 million birds every day, typically on high-speed automated production lines. High-speed lines make it “simply impossible to adequately inspect every animal.”⁸⁶ Thousands of birds are eviscerated every hour on the same machine, without intervening decontamination. The guts of individual animals are aligned differently, and mechanized evisceration frequently tears the intestines, thus spreading fecal contamination on the exterior of the carcass and the muscle tissue. Since the same machine eviscerates thousands of birds an hour, it only takes one pathogen-infected bird to infect hundreds or thousands of other birds.⁸⁷ Further, at this line speed and with the minimal number of federal poultry inspectors required, an inspector generally has less than two seconds to thoroughly check each chicken’s chest, cavity, interior, and flesh for nearly a dozen diseases, bruises, cancers, lesions, or other defects, and fecal contamination.⁸⁸

⁸³ *Chicken: What you don't know can hurt you*, Consumer Reports, March 1998.

⁸⁴ In addition to the microbial pathogens for which FSIS spot-checks, there are other pathogens spread through animal feces for which FSIS does not test. For instance, Johne’s disease (also known as paratuberculosis) is primarily an intestinal infection of ruminant animals that has been linked to Crohn’s disease, a chronic, progressive, debilitating enteric disease in humans. It is caused by a bacterium in the same genus as the bacteria causing tuberculosis in humans, cattle, and other species. About 22 percent of dairy and 8 percent of beef herds in the United States are infected with Johne’s disease. The causative bacteria is excreted in the feces of infected cows. *Johne’s Disease in Cattle*, supra note 30.

⁸⁵ The generic E. coli spot-check system is not intended to prevent the sale of fecally contaminated products and is not used as a means to withhold or recall products from the consumer market. Moreover, the testing is too infrequent to provide adequate assurance that fecally contaminated products are not being sold.

⁸⁶ Safety Last, supra note 16, at 17, citing, Food Chemical News, *Consumer Groups Kick Off Push for Family Food Protection Act*, February 6, 1995.

⁸⁷ Public Citizen, *The Jungle 2000*, at 13, available at <<http://www.citizen.org/CMEP/rad-food/The%20Jungle%202000.PDF>>.

⁸⁸ Safety Last, supra note 16, at 17, citing Food Chemical News, *FSIS Should Include Microbial Testing in HACCP*, June 6, 1994.

The standard process for defeathering and chilling poultry contributes to the spread of pathogens. USDA allows poultry carcasses to be placed in hot water baths, called scalders, to loosen feathers. Contaminated birds are put in the same water with all other birds, potentially passing along infective bacteria.⁸⁹

Slaughter of cattle and pigs is executed by plant workers, not machines. At more than 300 cattle slaughtered per hour, and more than 1,000 pigs slaughtered every hour, the spread of feces is unavoidable.⁹⁰ Organs are torn and their contents spilled. Feces are smeared and splattered. Because feces may have already spread from one cow to another during transport, when cattle undergo the dehiding process, additional fecal contamination can result. Further, because pigs' hides are not removed during the slaughter process, they are put through a communal scalding tank, similar to the defeathering tank for chickens. Thus, contaminated carcasses are put in the same water with all other carcasses, potentially infecting the uncontaminated ones.

Until 1978, USDA required the condemnation of any carcass with visible fecal contamination. Thereafter, USDA began allowing carcasses contaminated with visible feces to be "reprocessed," rather than condemned.⁹¹ As long as feces are no longer visible after the corrective reprocessing action, the carcass may continue to be processed. However, attempts to remove visible fecal contamination do not ensure the absence of harmful bacteria.

For example, trimming where feces are visible cannot ensure the removal of all pathogens. Livestock carcasses can be steam vacuumed (hot water is sprayed on a carcass and then vacuumed off), washed with an acid rinse, or trimmed to remove fecal contamination. Steam vacuuming to remove fecal contamination from meat carcasses only removes "incidental visible contamination" and only reduces (not eliminates) bacterial counts.⁹² Chemical rinses may wash off visible traces of feces, but feces not visible to the naked eye (and associated pathogens), may remain on the carcass.⁹³ As reported by USDA's Agricultural Research Service ("ARS"), ARS chemical engineer Arthur I. Morgan states:

Industry has a hard time removing surface contaminants from meat because microorganisms hang on tenaciously. Many escape hot-water washes or sprays containing bactericide and surfactants....This is true even when exposure time and bactericide content are more than enough to sterilize a smooth surface. We've seen contaminants remain on meat even after we've used organic acid solutions and trisodium phosphate. One of the reasons that existing methods aren't very effective in killing the harmful microorganisms is because of the liquid nature of water. Water can't

⁸⁹ Studies have documented that the percent of poultry carcasses contaminated with salmonella increases during processing. William James, et al., *Cost Effective Techniques to Control Human Enteropathogens on Fresh Poultry*, Poultry Science, 1993:72;1174-6.

⁹⁰ Joby Warrick, *An Outbreak Waiting to Happen: Beef Inspection Failures Let In a Deadly Microbe*, The Washington Post, April 9, 2001, at A1.

⁹¹ 9 C.F.R. § 310.18 (livestock); § 381.91 (poultry).

⁹² USDA Announces Approval of Trial Tests for Steam Process to Remove Contamination from Meat Carcasses, Release No. 0262.95, available at <<http://www.usda.gov/news/releases/1995/03/0262>>.

⁹³ Sandy Bishop, Quality Assurance Director at Wayne Poultry Division, Continental Grain Co., Gainesville, GA. Poultry, *Processing Methods: Eliminating Fecal Contamination* (October 1998), available at <<http://www.meatingplace.com/articles/p1182.asp>>.

reach all the contaminated surfaces. Feather, hair, or scale follicles are large enough to hide bacteria, but too small to admit a liquid wash or spray. An impossibly high water pressure would be needed to overcome the capillary pressure in a pore just large enough to house a bacterium.⁹⁴

While condemnation rates obviously dropped dramatically after this rule went into effect—because condemnation was no longer required by USDA for meat and poultry with fecal contamination—the actual outcome is that consumers are consuming more meat and poultry that once was, and potentially still is, contaminated when eaten.

A policy that only addresses visible fecal contamination is sorely inadequate. Not only can otherwise visible feces not be seen because of the speed involved in slaughtering and processing the animals, but traces of feces too small to be seen by the naked eye can carry pathogens and other potential health hazards.⁹⁵ Since feces are the carrier for pathogenic bacteria, a more comprehensive policy that addresses all fecal contamination is necessary.

B. Meat and Poultry Contaminated with Feces Are “Adulterated” under the FMIA and the PPIA.

As set forth above, under the FMIA and the PPIA, meat or poultry is “adulterated” if

- i) it bears or contains any poisonous or deleterious substance which may render it injurious to health; OR
- ii) if a substance is not an added substance, the meat or poultry is adulterated if the quantity of such substance in or on the product would ordinarily render it injurious to health, OR
- iii) if it consists in whole or part of any filthy, putrid, or decomposed substance, OR
- iv) is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.

Meat or poultry contaminated with feces clearly meets each of these criteria. Feces are a filthy, putrid substance, and food contaminated with feces is “unsound,” “unhealthful,” “unwholesome,” and “unfit for human food.”

In *U.S. v. Pilgrim Market Corporation*,⁹⁶ the government brought criminal charges against a slaughterhouse for distributing meat and poultry products that were adulterated because they were contaminated with rodent feces. The government asserted that the presence of rat feces caused the product to be adulterated because it consisted of a “filthy, putrid and decomposed substance” and “was unsound, unhealthful, unwholesome and otherwise unfit for human food.” As rodent feces are no more

⁹⁴ *Steaming Out the Salmonella Risk*, available at <<http://www.ars.usda.gov/is/AR/archive/oct97/steam1097.htm>>.

⁹⁵ USDA/ARS, *Battling Food-Poisoning Bacteria*, available at <<http://www.ars.usda.gov/is/AR/archive/feb99/food0299.htm>>.

⁹⁶ 944 F.2d 14 (1st Cir. 1991).

of a health hazard than livestock or poultry feces, there is no logical basis for distinguishing between the two substances in treating one as an adulterant and the other not.

Accordingly, meat or poultry contaminated with feces falls within the definition of “adulterated” under both the FMIA and the PPIA and should be treated as such.

C. Meat and Poultry Sold Commercially Should Be Free from Fecal Contamination.

Irrespective of the foodborne pathogen health risks posed to consumers who eat meat or poultry contaminated with feces, consumers expect and deserve to be able to purchase products free of fecal contamination. If consumers knew that the source of foodborne pathogens on poultry and meat is feces, many would choose not to purchase such products. But a disconnect has been created between the presence of feces on poultry and meat and the high rates of foodborne illness. In fact, a July 26, 2001, survey conducted by the Opinion Research Corporation International at the request of PCRM, found that 84 percent of Americans do not know that feces are the originating source for foodborne pathogens.⁹⁷ Thus, most consumers do not realize that when they get sick from eating meat or poultry, it is most likely because they ate fecally contaminated product.

Consumers are taught that pathogens are unavoidably part of meat and poultry products, as if no preventive action can be taken before the products reach their grocery cart. This is false and misleading. Consumers should be informed of the link between feces and foodborne illness in order to empower them to make educated purchasing decisions. The government should proactively inform consumers of this fact, just as it educates consumers about the dangers of foodborne pathogens. Declaring feces an adulterant and regulating it as such is an appropriate step in this education process.

D. Feces Should Be Regulated as an Adulterant.

Both the FMIA and the PPIA authorize FSIS to declare feces an adulterant and to regulate it as such.⁹⁸ FSIS relied upon these provisions when it declared *E. coli* 0157:H7 on raw ground beef an adulterant, declared salmonella and *L. monocytogenes* on ready-to-eat products adulterants, and when it promulgated its HACCP Rule. These provisions are equally applicable here. If infected feces were not on poultry and meat carcasses sold for consumption, the rates of food poisoning would drastically decrease. By not declaring feces an adulterant and by failing to impose stringent regulations to prevent its spread, FSIS is derelict in its duty to provide a pathogen-free meat and poultry supply.

A poultry and meat supply contaminated with feces should not be accepted by the American consumer nor considered inevitable by the federal government. FSIS should implement reforms that prevent fecal contamination. For example, FSIS could mandate less crowded and less stressful living conditions for animals raised for food; prohibit growth-promoting antibiotics; require fewer animals on trucks bound for slaughterhouses; mandate shorter distances to transport animals to slaughter; require the proper disposal of animal feces at all times; prohibit immersion tanks for poultry carcasses; prohibit scalding tanks for pig carcasses; mandate a reduction in permitted slaughter-line speeds; and implement and enforce a comprehensive testing program for coliform bacteria.

⁹⁷ See Survey attached hereto as Exhibit A.

⁹⁸ The Secretary of Agriculture has been granted broad authority to promulgate rules and regulations “necessary to carry out the Act[s].” 21 U.S.C. §§ 463, 621.

Further, FSIS's reliance on educating consumers about proper handling and cooking techniques clearly violates the FMIA and the PPIA. The meat and poultry inspection statutes prohibit passing any adulterated products at inspection, yet FSIS places the burden of decontaminating adulterated products on consumers. Doing so means that FSIS approves adulterated meat at inspection in violation of the law. PCRM is not advocating the discontinuation of safe-handling labels or consumer education programs, as there are some instances when pathogenic bacteria may contaminate a product through means other than fecal contact in a plant. Nevertheless, demanding the consumer "cook away the problem" or otherwise adhere to burdensome measures to perhaps prevent illness⁹⁹ should not be the course of action followed by the government to protect public health.

An additional important benefit of declaring and regulating feces as an adulterant is that it would encourage the meat and poultry industries to develop and implement effective production, slaughter, and processing interventions specifically aimed at preventing fecal contamination. Because regulating feces as an adulterant would increase the likelihood of detecting contamination—resulting in more frequent recalls and associated costs—companies would have a strong incentive to apply effective interventions.

Accordingly, to provide mandatory, and meaningful, protection to consumers, FSIS should declare feces an adulterant and regulate it as such.

II. FSIS Must Mandate the Application of a Biohazard Warning Label on Meat and Poultry Products to Prevent Misbranding.

Feces are a biohazard capable of transmitting infective agents to humans. Under most institutional circumstances, feces are treated as a biohazard because they are capable of causing disease in humans and "may pose a health risk to either individuals, the community, or both, if not handled or treated properly."¹⁰⁰ For instance, potentially contaminated animal carcasses must be packaged, labeled, and shipped as a biohazard.¹⁰¹ In a medical setting, feces per se and animal carcasses which may be contaminated with pathogenic bacteria and, therefore, contaminated with feces, are considered biohazards and regulated as "medical waste" consistent with specific restrictions to minimize human exposure—mandatory incineration or disposal in a biohazard container.¹⁰² In particular, fecally

⁹⁹ For instance, to prevent *E. coli* O157:H7 food poisoning, the government recommends always testing meat with a thermometer. If consumers suspect that a product such as ground beef in hamburger has not been cooked sufficiently, not only should they not eat that product, but they should also get a new bun and a new plate. The government also recommends keeping raw meat separate from all other foods in preparation, thereby necessitating two cutting boards and enough counter space to keep everything separate; washing hands, counters, and utensils with hot soapy water after they touch any raw meat; never placing cooked hamburgers or ground beef or other products on the unwashed plate that held raw meat; and washing meat thermometers in between tests of food that require further cooking. See *What can you do to prevent E. coli O157:H7 infection?*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm>.

¹⁰⁰ See Walter Reed Army Medical Center's Regulation No. 40-2, Medical Services Waste Disposal (August 25, 1999), citing Environmental Protection Agency regulations.

¹⁰¹ Interstate Shipment of Etiologic Agents, 42 C.F.R. § 72.3.

¹⁰² For examples, see Duke University's Medical Waste Management guidelines, available at <<http://www.safety.duke.edu/SafetyManuals/University/safman73.htm>>, and Ohio State University's

contaminated animal carcasses would be sealed in special leakproof, puncture-resistant bags labeled “biohazard” and disposed of in a manner that will prevent human health hazards.¹⁰³

The FMIA and the PPIA require USDA to protect consumers from adulterated and misbranded poultry and meat, not only through inspections at the plants, but also through officially-approved labels affixed to such poultry and meat. Under these statutes, meat or poultry is misbranded if it does not bear, in addition to the official inspection legends, “such other information as the Secretary [of Agriculture] may require...to assure that [the products] will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the product in a wholesome condition.”¹⁰⁴ Current regulations require the application of the official inspection legend on all poultry and meat products, and safe-handling instructions on all raw poultry and meat products. These labels are false and misleading and unduly confusing to the consumer, constituting misbranding.

The USDA inspection legend, which has been applied to meat for almost a century and to poultry since 1957, is intended to convey to the consumer that meat and poultry products are safe to eat. Consumers have predictably become accustomed to this guarantee of safety from their government. However, it is now widely recognized that eating meat and poultry is not safe from the standpoint of microbial contamination unless the consumer takes specific delineated actions to kill foodborne pathogens. USDA conservatively estimates that salmonella are present in 10 percent of chickens, 7 percent of pigs, 4 percent of ground beef, 14 percent of ground chicken, and 30 percent of ground turkey;¹⁰⁵ that between 60 to 80 percent of chilled whole birds at processing facilities are contaminated with campylobacter;¹⁰⁶ and, that, at slaughter, 17 percent of pig carcasses are contaminated with campylobacter.¹⁰⁷ Microbiological tests conducted on behalf of *Consumer Reports* revealed that 63 percent of store-bought chickens are contaminated with campylobacter and 16 percent contaminated with salmonella.¹⁰⁸ A current FSIS training video for inspectors states, “We expect [salmonella] contamination to be on raw product.”¹⁰⁹ As evidenced by FSIS’s food-safety programs, consumers are advised to treat every piece of raw meat or poultry as if it is contaminated with pathogenic bacteria.

Thus, application of the inspection legends on poultry and meat lulls consumers into a false sense of security about the poultry and meat they purchase and consume. Trying to address the false and misleading nature of the inspection legends, the government authorized the affixing of safe-handling instructions. However, the language of the safe-handling label is confusing and contradictory. It starts by advising that the product passed USDA inspection—which means to a consumer that the product is unadulterated and safe to eat—then indicates the necessity for the consumer to “properly” handle and cook the product because the product is not safe to eat.

Guidelines for Research and Biomedical Waste Disposal, available at <<http://www.biosci.ohio-state.edu/~jsmith/guideline.pdf>>.

¹⁰³ See Walter Reed Army Medical Center’s Regulation No. 40-2, *supra* note 100.

¹⁰⁴ 21 U.S.C. §§ 453(h)(12), 601(n)(12).

¹⁰⁵ USDA/FSIS, *Progress Report on Salmonella Testing of Raw Meat and Poultry Products, 1998-2000*, available at <<http://www.fsis.usda.gov/ophs/haccp/salmdata2.htm>>.

¹⁰⁶ 65 Fed. Reg. 75,187-02, *supra* note 20.

¹⁰⁷ USDA/ARS, *Battling Food-Poisoning Bacteria*, available at <<http://www.ars.usda.gov/is/AR/archive/feb99/food0199.htm>>.

¹⁰⁸ *Chicken: What you don’t know can hurt you*, *supra* note 83.

¹⁰⁹ USDA/FSIS, *Sampling Raw Meat and Poultry for Salmonella*.

As presented throughout this Petition, the fact that meat and poultry are not safe to eat from a microbiological perspective is most likely due to fecal contamination. Consumers deserve truthful, unambiguous labels. The labels should make clear that the government has not, and cannot, guarantee any meat or poultry product as safe to eat. In order to do so honestly and effectively, FSIS should mandate the application of a biohazard label on all poultry and meat products. The text of the biohazard warning label should unequivocally warn of the likely presence of feces and the concomitant health hazard, stating: “Biohazard: This product may be contaminated with feces and, therefore, hazardous to your health.”

FSIS is not only authorized to require warning labels on poultry and meat products, but, in this case, it is required to do so, contrary to the 1974 case American Public Health Association v. Butz.¹¹⁰ In Butz, a case decided 27 years ago, the court held that USDA inspection labels on meat and poultry that had been inspected and passed were not false and misleading so as to constitute misbranding, despite the fact that they did not contain a warning about foodborne pathogens and instructions for safe handling. Rather, the court noted, a consumer education campaign was sufficient to address the problems associated with foodborne illness caused from eating contaminated meat and poultry. In support of its decision, the court presumed that the presence of salmonella did not make meat or poultry adulterated,¹¹¹ that microscopic examination of poultry and meat was unrealistic, and that “American housewives and cooks normally are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis.”¹¹² Thus, although the application of warning labels was not precluded, the court determined that, at that time and under those circumstances, they were not required. Present circumstances make the Butz ruling inapplicable today.

Since 1974, FSIS has conducted a massive and targeted food safety campaign to inform consumers about safe handling and cooking of meat and poultry products. FSIS instituted a toll-free, nationwide food-safety hotline and conducts myriad food-safety campaigns directed at such specialized audiences as food handlers, institutions, health professionals, and at-risk populations, as well as food handlers in the home.¹¹³ Moreover, despite FSIS’s previous protestations that safe-handling instructions were unnecessary, it began mandating their application on all raw poultry and meat products in 1994.¹¹⁴ FSIS has even imposed microbial testing programs for various pathogens. Salmonella, which USDA argued in 1974 was not an adulterant, has since been declared an adulterant if found on some meat and poultry products.¹¹⁵

¹¹⁰ 511 F.2d 331 (D.C. Cir. 1974).

¹¹¹ The conclusion that “the presence of salmonella in meat does not constitute adulteration within the meaning of the [FMIA] was plainly dictum which did not reflect consideration of any factual basis or legal analysis of the adulteration provision of that Act.” Seabrook International v. Harris, 501 F.Supp. 1086 (D.D.C. 1980).

¹¹² APHA v. Butz, 511 F.2d at 334.

¹¹³ Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 58 Fed. Reg. 43,478 (Interim Rule August 16, 1993).

¹¹⁴ Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 59 Fed. Reg. 14,528 (March 28, 1994). In fact, USDA reversed its 1974 opinion on safe-handling instructions to settle a subsequent lawsuit filed to enjoin USDA from affixing the official inspection legend to poultry and meat unless it was accompanied by a warning and safe-handling label. 58 Fed. Reg. at 43,482, supra note 113.

¹¹⁵ Performance Standards for the Production of Processed Meat and Poultry Products, 66 Fed. Reg. 12,589 (proposed February 27, 2001); FSIS Directive 10,240.1, supra note 67.

These efforts, while important, have not sufficiently stopped the spread of foodborne pathogens. In fact, since the Butz case, several new pathogens have emerged and inflicted further harm to our nation's health. The first *E. coli* 0157:H7 outbreak occurred in 1982, and, since that time, this pathogen has caused hundreds of deaths and thousands of illnesses.¹¹⁶ *L. monocytogenes* was just recently recognized, but is now considered one of the most dangerous pathogens in our food supply.¹¹⁷ *Campylobacter* is one of the most prevalent forms of food poisoning, sickening at least 1 percent of our population annually.¹¹⁸

Further, eating habits have changed, resulting in reduced personal control over the safety of the food consumed. For example, compared to 1974, Americans today eat in restaurants far more often, eat significantly more "consumer-ready" prepared and processed poultry and meat, and prepare their own food considerably less often.¹¹⁹ Thus, the circumstances relied upon by the Butz court are notably, and materially, different from the situation today. Public education efforts and safe-handling instructions have failed to adequately attack the prevalence of foodborne illness. Despite implementation of HACCP, foodborne illness rates remain unacceptably high.

Given the continued health threat posed to consumers from eating fecally contaminated poultry and meat, FSIS must exercise its authority under the FMIA and the PPIA to require a biohazard warning label on all poultry and meat products. Otherwise, current inspection labels are false and misleading under the FMIA and the PPIA, constituting misbranding.

III. The Authorized Poultry Inspection Legend Should Be Modified to Exclude the Word "Wholesome."

USDA has discretion to regulate the text of the poultry inspection legend.¹²⁰ Using its discretion, the only inspection legend authorized for poultry reads: "Inspected for wholesomeness by United States Department of Agriculture." USDA regulations advise that the "Inspected for Wholesomeness" seal is intended to inform consumers that poultry was found to be unadulterated and, thus, free of disease, not decomposed, and to be otherwise fit for human consumption.¹²¹ Now, however, as explained on FSIS's Web site, the "inspected for wholesomeness" label merely "insures the chicken is free from visible signs of disease."¹²² Based on this new and distorted interpretation of the poultry inspection legend, the presence of feces not visible to the naked eye, as well as the presence of every pathogenic bacteria known to contaminate meat and poultry, would not make the product unwholesome.

¹¹⁶ Mead P, Slutsker L, Dietz V, McCaig L, Bresee J, Shapiro C, Griffin PM, and Tauxe RV. *Food-Related Illness and Death in the United States*, Emerging Infectious Diseases, September/October 1999; 5:5, available at <<http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>>.

¹¹⁷ CDC/DBMD, *Listeriosis*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm>.

¹¹⁸ CDC/DBMD, *Campylobacter*, available at <http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm>.

¹¹⁹ USDA/ERS, *Food Away From Home: America's Changing Food Choices*, Food Review, January-April 1999;22:1.

¹²⁰ As set forth above, USDA was not granted wide discretion for the language of the meat inspection legend.

¹²¹ 9 C.F.R. § 381.1.

¹²² FSIS Consumer Education and Information. *FOCUS ON: Chicken* (September 2000), available at <<http://www.fsis.usda.gov/oa/pubs/chicken.htm>>.

As currently evidenced by *Fight Bac!*, the *Thermy Campaign*, and other FSIS consumer education programs, FSIS has made clear its belief that, under current inspection regulations, it cannot guarantee a fecal- or foodborne pathogen-free poultry supply. Since FSIS cannot provide any degree of assurance that the poultry it inspects is unadulterated, free from fecal contamination, or wholesome—and, because contamination is, in fact, common and even expected by FSIS—use of the word “wholesome” should be discontinued in the official inspection legend. The government should not, and cannot, affix a seal that misleads consumers and may increase the incidence of foodborne illness and death.

The misleading “Inspected for Wholesomeness” inspection certificate affixed to poultry should be modified to protect consumers.

ECONOMIC IMPACT

I. The Economic Cost of Declaring and Regulating Feces as an Adulterant Will Be Outweighed by the Reduction in Costs Associated with Foodborne Illness.

The cost to the taxpayer for declaring and regulating feces as an adulterant is minimal. No formal administrative procedures are required to declare meat and poultry products contaminated with feces adulterated or to regulate feces as an adulterant.¹²³

Further, as PCRM is not recommending what specific actions FSIS should take to regulate fecal contamination, the determination of the expected economic impact to industry is premature at this time. Nonetheless, if effective regulations are imposed that prevent the occurrence of infected feces in animals used for food, the spread of feces on animals, or the rate of fecal contamination on meat and poultry products, the rate of foodborne illness in this country would decrease dramatically. Given that foodborne illness in this country is estimated to cost, at a minimum, \$6.9 billion annually, any cost to industry would be significantly outweighed by a reduction in public health costs, both financial and otherwise.

¹²³ See *Texas Food Industry Association v. Espy*, 870 F.Supp. 143 (W.D. Texas 1994). In *Texas Food Industry*, USDA announced—without prior notice, opportunity for comment, or any anticipated rulemaking—that ground beef contaminated with *E. coli* O157:H7 is adulterated under the FMIA, creating accountability for the presence of the pathogen in ground beef. Tied to the new definition of *E. coli* O157:H7 was a limited microbiological testing program. Prior to this declaration, USDA had treated all pathogen-contaminated meat as unadulterated. When this USDA announcement was challenged by the meat industry as a violation of the Administrative Procedure Act (“APA”), the court held in favor of USDA. In particular, the court found that USDA had the authority to mandate testing for this pathogen without engaging in notice-and-comment rulemaking because it was a “procedural rule.” Further, USDA’s declaration that ground beef contaminated with *E. coli* O157:H7 was an adulterant was held by the court to be an interpretive rule exempt from the notice-and-comment procedures under the APA. Thus, USDA was not required to “engage in substantive rule making as a predicate to considering a particular substance an adulterant.”

II. The Economic Cost of Mandating a Biohazard Warning Label on Meat and Poultry Products Will Be Outweighed by the Reduction in Costs Associated with Foodborne Illness.

The economic analysis for the application of a biohazard warning label is very similar to the economic analysis for the application of safe-handling instructions in 1994.¹²⁴ Thus, the requirement that a biohazard warning label be affixed to all meat and poultry products would affect slaughter and processing facilities and retail establishments differently. For products prepackaged by the slaughter or processing establishment, the label would be made part of the wrapping, as is currently done for USDA inspection legend and safe-handling instructions. Consequently, as with the safe-handling labels, slaughter and processing facilities would only face upfront, one-time costs, but would not experience recurring costs.

For retail stores, the biohazard label could be incorporated onto the existing safe-handling label or a store's weight and price information label, both of which are currently affixed to poultry and meat products. Retail stores may need to upgrade equipment to accommodate a different or larger label, but there would be no additional labor costs. There will also be recurring costs in the form of the cost for each label that is applied. Regardless of the manner in which those labels are formatted, the recurring costs for the labels will be very low, especially in light of the net societal benefit.

III. The Economic Cost for Changing the Poultry Inspection Legend Is Minimal.

Changing the poultry inspection legend would impose a minimal up front, one-time cost to both processing and retail facilities, similar to the up-front, one-time costs imposed for the biohazard label. The cost for the modified label would result in a net societal benefit.

CONCLUSION

Poultry and meat carry bacteria that make people sick because the products were at some point contaminated with feces carrying pathogenic bacteria. The rules requested herein will reduce the risk of foodborne illness associated with the consumption of fecally contaminated poultry and meat products. Reduced risk would lead to public health benefits that are measured in reduced medical costs, reduced time lost from work, reduced pain and suffering, and reduced loss of life. In 1972, USDA fought—and won—a legal battle to prevent the application of safe-handling instructions on meat and poultry products. At that time, USDA asserted that a consumer education campaign was sufficient to remedy the problems associated with foodborne illness. But consumer education has not been sufficient. Thus, in 1994, USDA agreed that safe-handling instructions were necessary to prevent foodborne illness and issued regulations regarding same. Still, that step proved grossly insufficient. Beginning in 1996, USDA issued final regulations introducing HACCP into the processing and slaughter operations of poultry and meat products. As the evidence shows, however, this is still not enough. The time is ripe to directly attack the problem—to affect means to prevent fecal contamination and to adequately warn consumers to protect themselves.

¹²⁴ 59 Fed. Reg. 14,528, supra note 114.

Accordingly, PCRM hereby requests that FSIS:

1. Declare that any meat or poultry product contaminated with feces is adulterated, and create accountability for the presence of feces by regulating it as an adulterant;
2. Amend Title 9 of the Code of Federal Regulations to mandate a biohazard warning label on all meat and poultry products that states: “Biohazard: This product may be contaminated with feces and, therefore, hazardous to your health”; and,
3. Amend Title 9 of the Code of Federal Regulations to change the authorized poultry inspection legend to preclude the word “wholesome” or any other descriptive word that implies that poultry products are safe to eat.