Interpretive Summary

Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef

PREFACE

The Office of Public Health and Science in the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS)—with input from other federal agencies, industry, and the public—conducted an assessment of the risk of illness associated with *Escherichia coli* O157:H7 in ground beef. This risk assessment details our current state of knowledge about (1) the occurrence of *E. coli* O157:H7 in cattle, carcasses, and beef trim; in retail ground beef; and in ground beef servings consumed in the United States; and (2) the subsequent risk of illness associated with consuming ground beef contaminated with *E. coli* O157:H7.

This Interpretive Summary provides an overview of the *E. coli* O157:H7 risk assessment. Its purpose is to briefly describe the material covered in the complete risk assessment, including background information on *E. coli* O157:H7 and related illness, the techniques and data used to develop the risk assessment, the results of the risk assessment, and the limitations and implications of those findings.

INTRODUCTION

E. coli O157:H7 was first recognized as a human pathogen in 1982, when it was associated with two outbreaks of bloody diarrhea in Oregon and Michigan involving the consumption of hamburgers from a fast-food chain. Since then, *E. coli* O157:H7 has become a public health concern worldwide, causing outbreaks in the United States, Japan, Canada, Scotland, and Argentina. In 1999, the Centers for Disease Control and Prevention (CDC) estimated that 76 million foodborne illnesses occur annually in the United States. An estimated 62,000 cases of symptomatic *E. coli* O157:H7 infections occur annually in the United States due to foodborne exposures, resulting in approximately 1,800 hospitalizations and 52 deaths. As many as 3,000 cases may develop hemolytic uremic syndrome annually. Surveillance data indicate that the highest incidence of illness from *E. coli* O157:H7 occurs in children under 5 years of age.

Since 1982 (when *E. coli* O157:H7 emerged as a foodborne pathogen in the United States), FSIS has taken several regulatory measures to protect public health against this pathogen. In August 1994, FSIS declared *E. coli* an adulterant. Under this policy, raw chopped or ground beef products that contain *E. coli* O157:H7 required further processing to destroy *E. coli* O157:H7. On October 17, 1994, FSIS initiated a microbiological testing program for *E. coli* O157:H7 in raw ground beef in meat plants and retail stores. The initial testing program was established and designed to test approximately 5,000 raw ground beef samples, 50% from federally inspected plants and 50% from retail stores. In 1998, the sample size was increased from 25 grams to 325 grams to increase test sensitivity for this organism.

In addition to improved sampling for *E. coli* O157:H7 in ground beef, FSIS initiated a risk assessment of *E. coli* O157:H7 in March 1998. The goal was to produce a baseline risk assessment that reflects current practices along the farm-to-table continuum and accurately assesses the likelihood of human morbidity and mortality associated with the consumption of ground beef contaminated with *E. coli* O157:H7 in the United States.

The primary use of this risk assessment is to assist FSIS in reviewing and refining its risk reduction strategy for *E. coli* O157:H7 in ground beef. The risk assessment produces scientific support for the development of regulatory impact assessments to support FSIS rulemaking, the identification of critical control points and critical control limits in Hazard Analysis and Critical Control Point (HACCP) systems for ground beef, risk-based sampling plans for FSIS inspectors to verify that industry HACCP systems are meeting regulatory standards for *E. coli* O157:H7 in ground beef, and the identification of food safety research on *E. coli* O157:H7 in ground beef.

FSIS has based the risk assessment of *E. coli* O157:H7 in ground beef on a comprehensive review of the available literature and data. This risk assessment includes data available through July 2001. The baseline risk assessment follows the generally accepted framework for microbial risk assessments with four primary components: (1) hazard identification, (2) exposure assessment, (3) hazard characterization, and (4) risk characterization (Figure 1). The result of the risk assessment is a computer model that can be refined and updated for use in future risk assessments for ground beef products as new information and data become available.

HAZARD IDENTIFICATION

E. coli O157:H7, a Shiga toxin-producing *E. coli*, was first recognized as a human pathogen in 1982, when it was associated with two outbreaks of hemorrhagic colitis (bloody diarrhea) in Oregon and Michigan involving the consumption of hamburgers from a fast-food chain. The continued occurrence of large outbreaks and an increase in the incidence of reported cases have led to the designation of *E. coli* O157:H7 as an emerging pathogen. Since 1982, epidemiologic studies have shown that *E. coli* O157:H7 can be transmitted through water (by drinking or swimming in contaminated water), food, and person-to-person contact, especially in a daycare setting. However, ground beef continues to be a significant source of *E. coli* O157:H7 infection in humans.

Multiple genetic subtypes of *E. coli* exist; many of these are part of the normal mammalian intestinal flora and do not cause disease in humans. *E. coli* strains that cause diarrheal illness are categorized into specific groups based on virulence properties, mechanisms of pathogenicity, and clinical syndromes. These categories include enteropathogenic *E. coli* (EPEC), enterotoxigenic

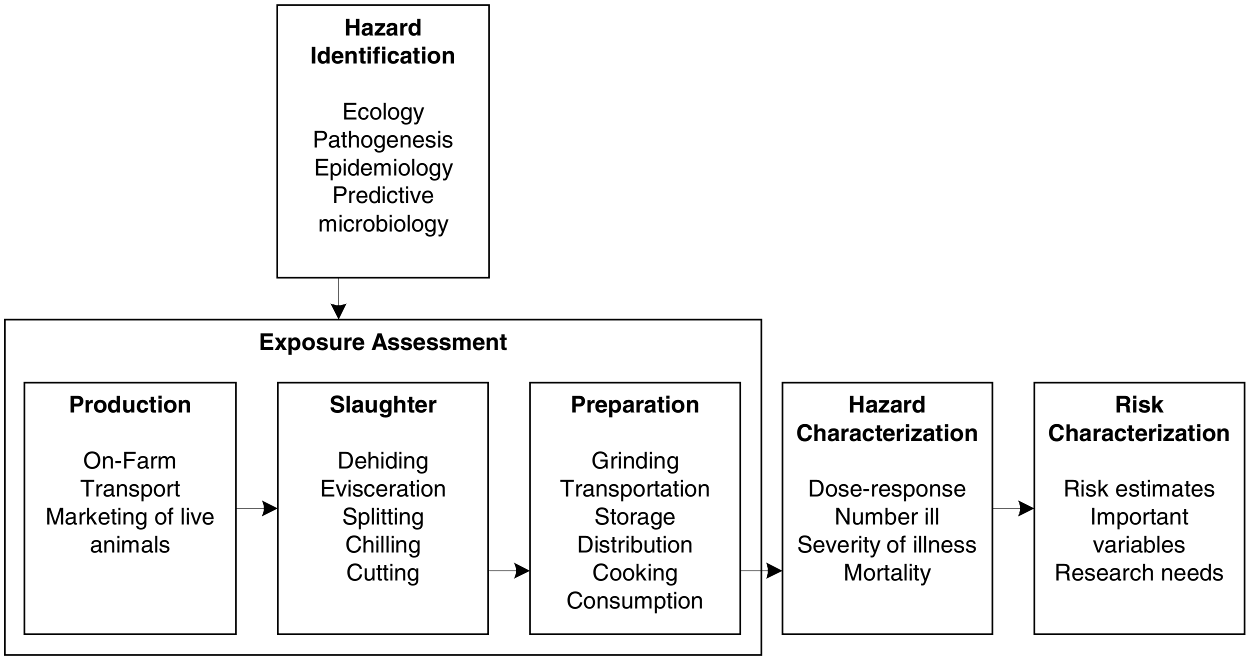


FIGURE 1 Farm-to-table risk assessment model for *E. coli* O157:H7 in ground beef.

E. coli (ETEC), enteroinvasive *E. coli* (EIEC), diffuse-adhering *E. coli* (DAEC), enteroaggregative *E. coli* (EaggEC), and Shiga toxin-producing *E. coli* (STEC). *E. coli* O157:H7 is in the STEC group and can produce Shiga toxin 1, Shiga toxin 2, or both. Shiga toxin production alone may not be enough to cause illness. In addition to Shiga toxin, some strains of STEC contain genes that code for the ability to attach and damage intestinal tract cells, causing what is commonly referred to as attaching and effacing lesions. When a STEC has the full complement of these virulence genes and has been associated with an illness such as bloody diarrhea, they are often referred to as enterohemorrhagic *E. coli* (EHEC).

The primary reservoir for *E. coli* O157:H7 is healthy cattle. *E. coli* O157:H7 can be transmitted to humans by contaminated food or water or directly from person-to-person. Foodborne *E. coli* O157:H7 cases in the United States have been linked to contaminated cattle-derived products such as ground beef or milk. Increasingly, fresh produce (such as alfalfa sprouts or lettuce) or related products (such as unpasteurized or untreated cider or juice) have been implicated in disease outbreaks. It is possible that the raw produce and related products are contaminated in the field with the feces or by water contaminated with the feces of infected animals.

E. coli O157:H7 has been isolated from the feces or gastrointestinal tract of cattle, sheep, horses, pigs, turkeys, dogs, and a variety of wild animal species; however, epidemiologic studies have found that cattle manure is the source of most human *E. coli* O157:H7 infections. *E. coli* O157:H7 has also been isolated from bodies of water (e.g., ponds, streams), wells, and water troughs and has been found to survive for months in manure and water trough sediments.

Colonization of the gastrointestinal tract for longer than 2 to 3 months has not been reported in any species, although only cattle, sheep, and humans have been sampled with sufficient intensity to assess duration of carriage. Despite this finding, *E. coli* O157:H7 has been described as "ubiquitous" in dairy and beef cattle and is present on most farms or feedlots at least some of the time. This widespread prevalence in cattle has been attributed to the organism's ability to survive for at least 4 months in water trough sediments, providing an ongoing source of exposure to cattle. *E. coli* O157:H7 is also present in purchased animal feeds; therefore, such feeds may be an important route by which *E.* coli O157:H7 is disseminated to farms. From the farm, *E. coli* O157:H7 contamination of meat occurs when beef carcasses come into contact with hides and feces during the slaughter process.

Human infection with *E. coli* O157:H7 results in a clinical spectrum of illness that ranges from mild to severe and includes asymptomatic infection, nonbloody diarrhea, bloody diarrhea, hemolytic-uremic syndrome (HUS)—a condition that includes destruction of red blood cells, problems with blood clotting, and kidney failure—and thrombotic thrombocytopenic purpura (TTP) —a condition that is similar to HUS but usually occurs over a longer period of time and may also cause changes in mental status. Between 2% and 20% of patients develop HUS following *E. coli* O157:H7 infection. Reportedly, 0.6% of patients died as a result of their infection. A recent study published in the *New England Journal of Medicine* found that treatment with antibiotics may have contributed to the development of HUS in children infected with *E. coli* O157:H7. In general, population subgroups at risk for the more severe clinical manifestations of infection with *E. coli* O157:H7 include the very young and the elderly.

A number of factors have a significant influence on the survival and growth of *E. coli* O157:H7 in food, including temperature, pH, salt, and water activity. Studies on the thermal sensitivity of *E. coli* O157:H7 in ground beef have revealed that the pathogen has no unusual resistance to heat, and heating ground beef sufficiently to kill typical strains of *Salmonella* will also kill *E. coli* O157:H7. Thermal pasteurization of milk has also been determined to be an effective treatment. The optimal temperature for growth of *E. coli* O157:H7 is approximately 37°C (98.6°F) and the organism will not grow at temperatures below 8° to 10°C (46° to 50°F) or above 44° to 45°C. *E. coli* O157:H7 survives freezing, with some decline in the concentration of *E. coli* O157:H7.

E. coli O157:H7 has been reported to be more acid resistant than other *E. coli*. Acid resistance enhances the survival of *E. coli* O157:H7 in mildly acidic foods and may explain its ability to survive passage through the stomach and cause infection at low doses. The ability to be acid resistant varies among strains and is influenced by growth phase and other environmental factors. Once induced, acid resistance is maintained for long periods of time during cold storage. Stationary-phase *E. coli* O157:H7 are more resistant to acid than growing cells. The presence of other environmental stresses, such as temperature or water activity stress, will raise the minimum pH for growth. *E. coli* O157:H7 survives in such foods as dry salami, apple cider, and mayonnaise, which were previously considered to be too acidic to support the survival of foodborne pathogens. Published literature contains conflicting reports about the efficacy of acid spray washing of beef carcasses. One study found that warm and hot acid sprays did not significantly reduce the concentration of *E. coli* O157:H7 on beef carcasses, while two other studies have found organic acids to be effective in reducing the presence of *E. coli* O157:H7 on beef carcasses. These apparently contradictory results may reflect differences in acid resistance among strains of *E. coli* O157:H7.

E. coli O157:H7 can survive for extended periods under conditions of reduced water activity while refrigerated; however, the organism does not tolerate high salt conditions.

EXPOSURE ASSESSMENT

The purpose of the exposure assessment is to estimate the occurrence and number of *E. coli O157:H7* organisms in servings of ground beef by modeling the processes involved from production of cattle on the farm to consumption of ground beef. The exposure assessment is divided into three modules: production, slaughter, and preparation. The production module estimates the herd and within-herd prevalence of *E. coli* O157:H7 infection in breeding cattle and feedlot cattle. Results from the production module are inputs for the slaughter module, which estimates the occurrence and number of *E. coli* O157:H7 organisms on carcasses and in beef trim. Results from the slaughter module are inputs for the preparation module, which estimates the occurrence and number of *E. coli* O157:H7 organisms in ground beef servings.

Production

The production module estimates the prevalence of *E. coli* O157:H7-infected cattle entering U.S. slaughter plants. It models culled breeding cattle (cows and bulls) and feedlot cattle (steers and heifers) from their points of origin through transit to the slaughter plant. About 80% of all cattle slaughtered in the United States are feedlot cattle. Culled breeding cattle and feedlot cattle are modeled separately in this risk assessment because the slaughter, processing, and distribution of meat from these types of cattle are different, and because sampling evidence suggests there may be differences in *E. coli* O157:H7 prevalence between these two types of cattle.

Most evidence on the occurrence and distribution of this organism in U.S. livestock was collected during surveys of farms and feedlots. It is assumed that imported beef originates from countries whose *E. coli* O157:H7 epidemiology is similar to the United States.

The production module estimates the prevalence of *E. coli* O157:H7-infected herds (herd prevalence) and feedlots (feedlot prevalence). Herd prevalence is the proportion of all breeding herds that contain one or more infected cattle. Feedlot prevalence is similar, but the reference population is U.S. feedlots. The production module also estimates the proportion of *E. coli* O157:H7-infected cattle within infected herds (within-herd prevalence) and feedlots (within-feedlot prevalence). Seasonal variability of within-herd and within-feedlot prevalence is also estimated.

Table 1 shows estimated prevalence of *E. coli* O157:H7 infected cattle in the United States. Generally, these results demonstrate that *E. coli* O157:H7 prevalence is significantly higher for feedlot cattle than for breeding cattle and that, for both types of cattle, prevalence is higher from June through September.

TABLE 1. Prevalence of *E. coli* O157:H7 Infected Cattle

Result	5th percentile	Mean	95th percentile
Breeding herd prevalence	55%	63%	72%
Feedlot prevalence	78%	88%	97%
Low prevalence season (October to May)			
Average within-herd prevalence	2%	3%	4%
Average within-feedlot prevalence	6%	9%	14%
High prevalence season (June to September)			
Average within-herd prevalence	3%	4%	5%
Average within-feedlot prevalence	21%	22%	24%

The production module simulates cattle entering the slaughter process via truckloads. Therefore, prevalence of infection within truckloads is this model's output and the first input to the slaughter module. For breeding cattle, about 45% of truckloads are predicted to have no infected cattle during the low prevalence season and 35% of truckloads are predicted to have no infected cattle during the high prevalence season (Figure 2). For feedlot cattle, the frequency of truckloads with no infected cattle is about 32% in the low prevalence season and 20% in the high prevalence season (Figure 3).

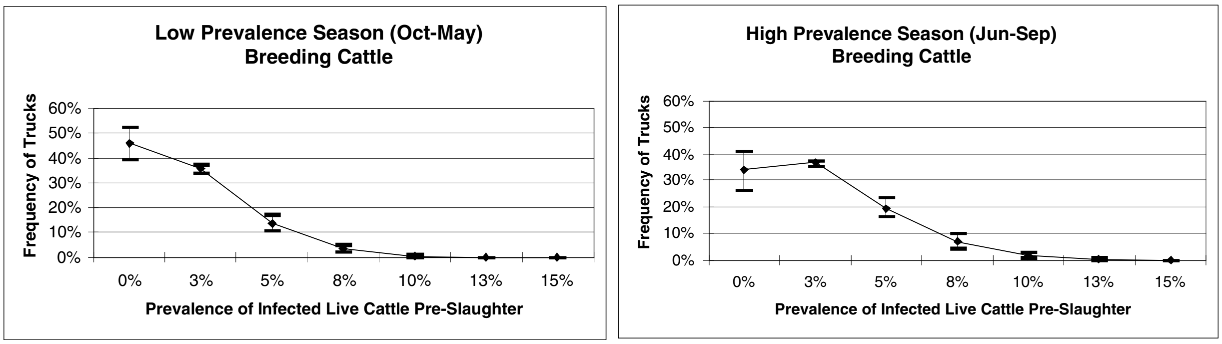


FIGURE 2 Comparison of seasonal distributions for prevalence of infected cattle within truckloads of breeding cattle sent to slaughter. Error bars show the 5th and 95th percentiles of uncertainty about frequency of trucks at each prevalence level.

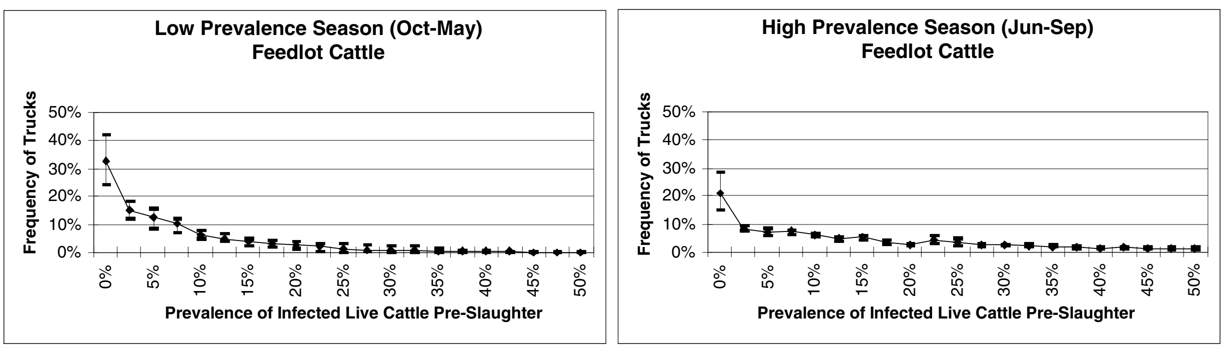


FIGURE 3 Comparison of seasonal distributions for prevalence of infected cattle within truckloads of feedlot cattle sent to slaughter. Error bars show the 5th and 95th percentiles of uncertainty about frequency of trucks at each prevalence level.

Slaughter

The slaughter module estimates the occurrence and extent of *E. coli* O157:H7 contamination as live cattle transition to carcasses, then to meat trim, and finally to aggregates of meat trim in 60-pound trim boxes or 2,000-pound combo bins destined for ground beef production. Truckloads of infected cattle simulated in the production module serve as inputs to the slaughter module.

Slaughter plants that handle culled breeding cattle and those that handle feedlot cattle are modeled separately. Greater than 90% of feedlot (steer/heifer) cattle are slaughtered in large facilities that handle more than 1,000 head per day, while 40% of culled breeding (cow/bull) cattle are slaughtered in such facilities. Additionally, slaughtering operations for the high (June to September) and low (October to May) prevalence seasons are modeled separately.

The slaughter module includes seven steps: (1) arrival of live cattle at slaughter plant, (2) dehiding, (3) decontamination following dehiding, (4) evisceration, (5) final washing, (6) chilling, and (7) carcass fabrication (i.e., creation of trim) (Figure 4). Although there are other steps that are normally part of the slaughter process (e.g., stunning, carcass splitting), these are not explicitly modeled. Generally, these other steps are incorporated into the seven steps of the model.

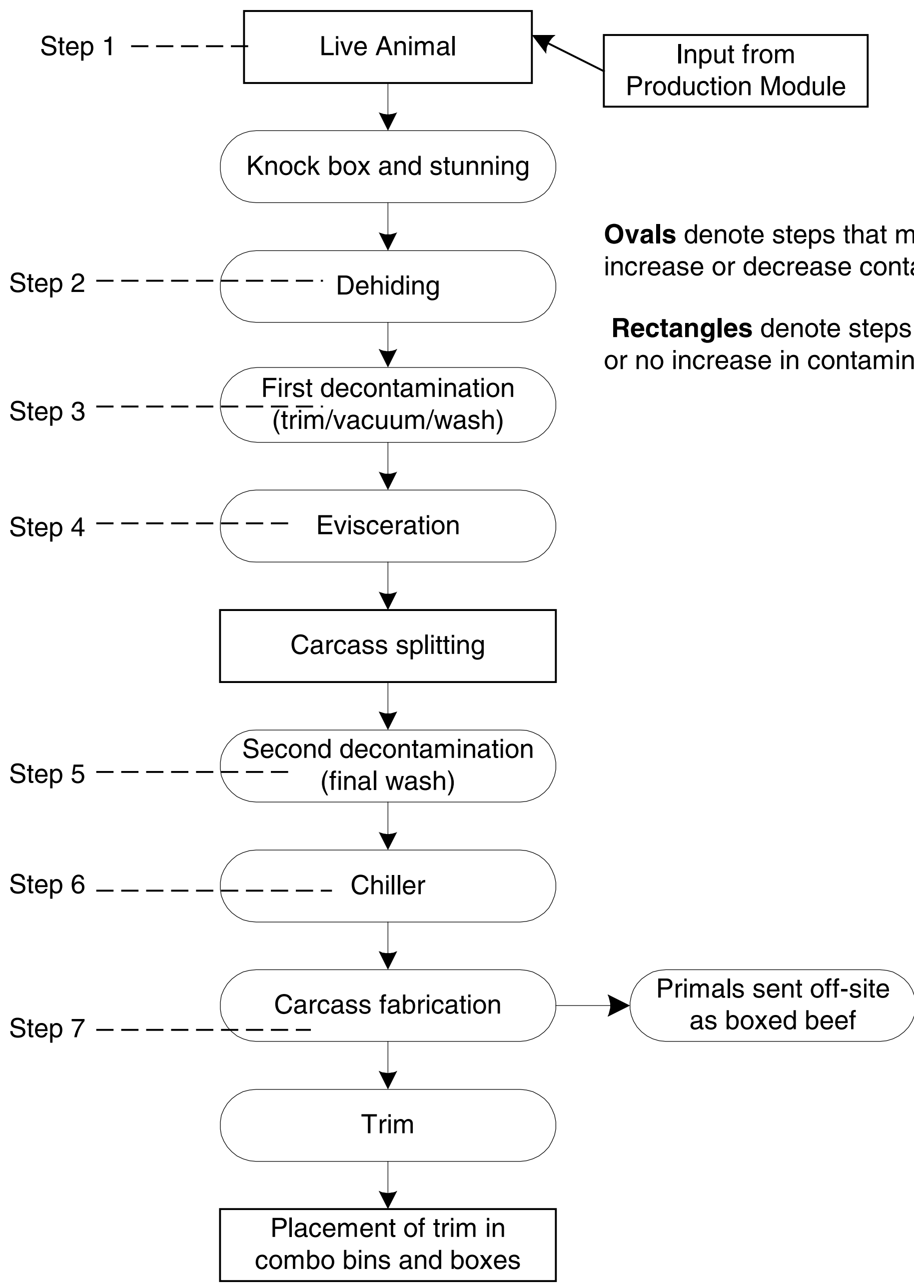


FIGURE 4 Steps modeled in the slaughter module.

The model assumes that contamination can increase or decrease at different steps of the process. It is possible that a decontamination process is completely effective in eliminating *E. coli* O157:H7 from a carcass, thereby reducing the prevalence of contaminated carcasses.

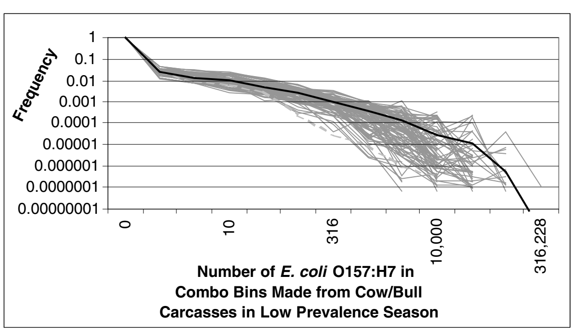
Cattle arrive at slaughter plants (Step 1) via truckloads with variable prevalences of infected cattle. Because slaughter lots may consist of multiple truckloads, each truck's prevalence is estimated in this step, and the total number of infected cattle in the lot is estimated based on the total number of infected cattle contributing to a combo bin.

Dehiding (Step 2) is the transition from live cattle to carcasses. The process of removing the hide creates the first opportunity for surface contamination of the carcass with *E. coli* O157:H7 and other pathogenic and nonpathogenic microbes. The number of *E. coli* O157:H7 organisms that initially contaminate a carcass depends on the level of infected cattle, the average concentration of *E. coli* O157:H7 per contaminated area, and the total area of a carcass that is contaminated. Contamination introduced during dehiding can be reduced during decontamination (Step 3). During decontamination, trimming, vacuuming, or washing of the carcass surface can reduce the number of organisms on contaminated carcass surfaces.

Evisceration (Step 4) is another opportunity for contamination to be introduced. If any part of the gastrointestinal tract is perforated during the evisceration procedure, *E. coli* O157:H7 contamination of muscle tissue can occur. Carcass splitting and final washing (Step 5) follows evisceration. During final washing, carcasses are washed or steam pasteurized.

Following final washing, the carcasses move to the chiller (Step 6), where *E. coli* O157:H7 contamination may again increase or decrease. After chilling, the carcasses are separated into smaller units that are used to produce whole-muscle cuts of beef (Step 7, fabrication). A by-product of this process for feedlot cattle is beef trim. Because carcasses from breeding cattle produce less valuable whole muscle cuts, greater proportions of these carcasses are converted to beef trim. The boneless meat trim from one animal is distributed based on fat content into multiple 2000-pound combo bins or 60-pound boxes, where it is mixed with trim from other cattle. Fabrication can also result in new or additional contamination through cross-contamination of work surfaces.

Figure 5 shows distributions of *E. coli* O157:H7 contamination in combo bins generated from the slaughter of cows and bulls (breeding cattle). During the low prevalence season, the average prevalence of combo bins containing no *E. coli* O157:H7 is 94%, but this frequency might range between 88% and 97% because of uncertainty in model inputs. During the high prevalence season, an average of 92% (ranging from 85% to 97%) of combo bins contain no *E. coli* O157:H7.



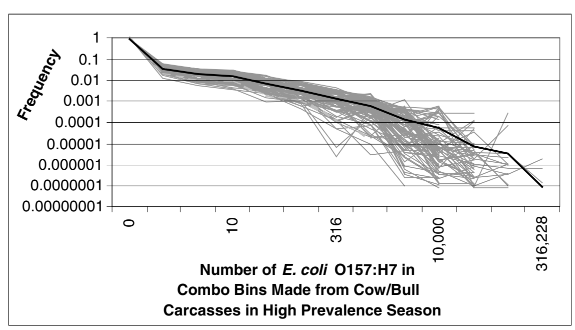


FIGURE 5 Comparison of seasonal distributions for number of *E. coli* O157:H7 in combo bins constructed from the slaughter of breeding (cow/bull) cattle. The dark lines are the mean distributions for each season.

Figure 6 shows distributions of *E. coli* O157:H7 contamination in combo bins generated from the slaughter of steers and heifers (feedlot cattle). During the low prevalence season, an average of 77% (ranging from 55% to 97%) of combo bins generated from steer/heifer carcasses contain no *E. coli* O157:H7. During the high prevalence season, 57% (ranging from 42% to 83%) of these combo bins contain no *E. coli* O157:H7. Differences in contamination of combo bins between types of carcasses and season are largely reflective of differences in incoming prevalence. Since boxes of beef trim are modeled from combo bins of beef trim, differences in contamination by season and cattle type reflect those for combo bins, though the level of contamination for 60-pound boxes is understandably lower than for 2,000 pound combo bins.

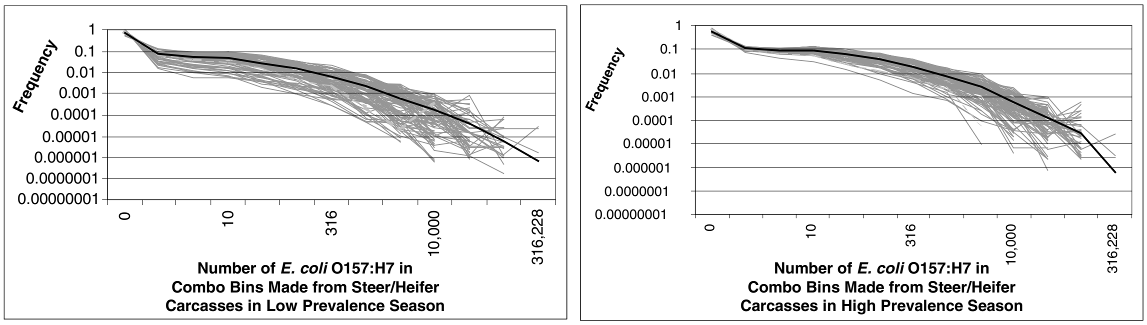


FIGURE 6 Comparison of seasonal distributions for number of *E. coli* O157:H7 in combo bins constructed from the slaughter of feedlot (steer/heifer) cattle. The dark lines are the mean distributions for each season.

Preparation

The preparation module simulates the annual consumption of approximately 18 billion ground beef servings. It considers the effects of storage and cooking on the amount of *E. coli* O157:H7 in contaminated servings.

Ground beef is consumed in many forms. Typical forms are hamburger patties, ground beef as a formed major ingredient (e.g., meatballs and meat loaf), and ground beef as a granulated ingredient (e.g., ground beef in spaghetti sauce). The model focuses on the first two forms. Because granulated ground beef has a relatively large surface area compared to volume, the effect of cooking on this product is considered to be similar to intact beef products, which are generally considered to be safe after cooking. Furthermore, products incorporating granulated ground beef are often subjected to further cooking. Consequently, these types of products are assumed to have no viable *E. coli* O157:H7 organisms and are not modeled. Furthermore cross-contamination of ground beef products is not modeled. The model, however, can serve as a starting point for analysis of the effects of cross-contamination on human exposures to *E. coli* O157:H7.

The preparation module consists of six steps. Five of these steps explicitly model growth, decline, or dispersion of *E. coli* O157:H7 contamination: (1) grinding, (2) storage during processing by the retailer or distributor, (3) transportation home or to hotels, restaurants, and institutions (HRI), (4) storage at home and “away from home” (i.e., HRI), and (5) cooking. Step 6 models the amount of ground beef consumed, which varies depending on the age of the consumer and the location where the meal was consumed.

Grinding (Step 1) transforms combo bins and boxes into ground beef. Combo bins are processed in large commercial facilities. Boxes are typically processed in smaller settings such as grocery stores. Multiple combo bins or boxes are combined, mixed, and extruded to produce finished ground beef with a specific fat content. Although the extent of *E. coli* O157:H7 contamination does not increase during the grinding process, contamination from a single combo bin or box can be dispersed during grinding to contaminate many individual ground beef servings.

Storage conditions at retail or wholesale (Step 2) provide an opportunity for *E. coli* O157:H7 levels to (a) increase as a result of time and temperature abuse or (b) decrease as a result of the effects of freezing ground beef. Step 3 models the effects of time and temperature during transportation on the level of *E. coli* O157:H7 after the ground beef is purchased. Step 4 models the storage of ground beef in the freezer or refrigerator prior to its preparation and consumption and provides another opportunity for increases or decreases in *E. coli* O157:H7 contamination in ground beef servings.

Ground beef is usually cooked prior to consumption (Step 5). Cooking can significantly reduce *E. coli* O157:H7 in ground beef servings. The model uses final internal product temperature data from a commercial food temperature database (Audits International 1999) to determine the level of reduction in *E. coli* O157:H7 contamination in ground beef servings.

Step 6 models consumption of *E. coli* O157:H7-contaminated ground beef servings, taking into consideration the age of the consumer and location where the meals were consumed.

Exposure Assessment Results

Grinder Loads

An intermediate output of the exposure assessment is the distribution of *E. coli* O157:H7 densities in grinder loads of ground beef made from 2,000-pound combo bins. Figure 7 shows the results of 100 simulations for grinders in the low and high prevalence seasons.

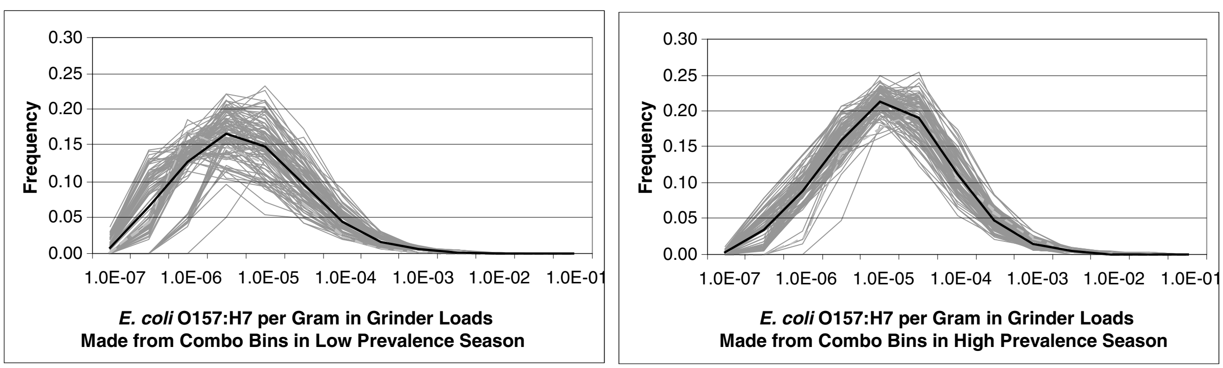


FIGURE 7 Frequency of ground beef contamination in contaminated grinder loads made from 2,000-pound combo bins in low and high prevalence seasons. Grinder loads that are not contaminated are not shown in this figure. The mean grinder load distribution is represented by the dark line.

Table 2 summarizes the prevalence of contaminated grinder loads for the 100 simulations depicted in Figure 7. Mean results indicate that 32% of the grinder loads in the low prevalence season and 14% of the grinder loads in the high prevalence season are not contaminated.

TABLE 2. Results of 100 Simulations for Grinder Loads Constructed from 2,000-Pound Combo Bins in the Low and High Prevalence Seasons

	Percent Contaminated Grinder Loads	
	Low Prevalence Season	High Prevalence Season
Mean	68%	86%
Minimum	28%	61%
5th percentile	40%	76%
50th percentile	71%	88%
95th percentile	84%	93%
Maximum	88%	94%

In the low prevalence season, between 40% (5th percentile) and 88% (95th percentile) of these grinder loads contained one or more *E. coli* O157:H7. In the high prevalence season, between 61% (5th percentile) and 94% (95th percentile) of grinder loads contained one or more *E. coli* O157:H7.

Human Exposures to E. coli O157:H7

The primary outputs from the preparation module are distributions describing the prevalence of *E. coli* O157:H7 in ground beef servings generated during low and high prevalence seasons. Figure 8 shows the results of 100 simulations for exposure distributions for the low and high prevalence seasons.

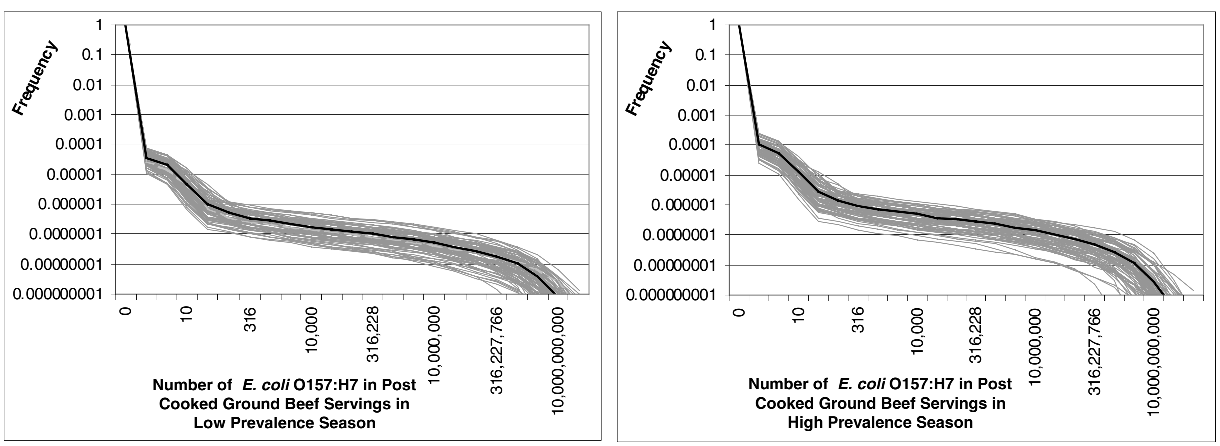


FIGURE 8 Frequency of exposure to various levels of *E. coli* O157:H7 during the low prevalence and high prevalence seasons. The mean exposure distribution is designated by the dark line.

As shown in Figure 8, very few cooked ground beef servings are expected to have surviving *E. coli* O157:H7 organisms present. Furthermore of the contaminated servings shown in Figure 8, about 95% have 10 or fewer *E. coli* O157:H7 organisms. Table 3 summarizes the simulations shown in Figure 8. Mean results indicate that 99.993% of cooked ground beef servings in the low prevalence season and 99.982% of cooked ground beef servings in the high prevalence season have no *E. coli* O157:H7 present.

Considerable uncertainty exists regarding the frequency of cooked ground beef servings that have one or more *E. coli* O157:H7 present. Table 3 shows that there is 90% confidence that the true frequency of contaminated servings lies somewhere between 1 in 36,000 and 1 in 7,600 in the low prevalence season and between 1 in 15,000 and 1 in 3,300 in the high prevalence season. Such a difference mirrors the difference noted in FSIS ground beef sampling data between the high and low prevalence seasons.

TABLE 3 Results of 100 Simulations Showing Percent of Post-Cooked Servings that Are Predicted to Have One or More Surviving *E. coli* O157:H7 in the Low and High Prevalence Seasons

	Percent Contaminated Servings	
	Low Prevalence Season	High Prevalence Season
Mean	0.007%	0.018%
Minimum	0.002%	0.004%
5th percentile	0.003%	0.007%
50th percentile	0.006%	0.019%
95th percentile	0.013%	0.030%
Maximum	0.014%	0.042%

HAZARD CHARACTERIZATION

Hazard characterization quantifies the nature and severity of the adverse health effects (i.e., illness or death) associated with the occurrence of *E. coli* O157:H7 in ground beef. For *E. coli* O157:H7, the precise relationship between the number of organisms consumed and the resulting adverse human health event is not known.

The *E. coli* O157:H7 dose-response function was derived using information from three sources: (1) the estimated annual number of symptomatic *E.* coli O157:H7 infections resulting from ground beef exposure, (2) the estimated number of contaminated ground beef servings from the exposure assessment, and (3) the lower and upper bound dose-response curves derived using surrogate pathogens. The lower and upper bound dose-response curves describe the uncertainty about the probability of symptomatic illness at an ingested dose level based on bounding (minimum and maximum) estimates and a most likely value within the bounds of the envelope.

A beta-Poisson function was chosen to represent the dose-response relationship. This functional form assumes that a single organism is capable of infecting and inciting illness in an individual and that organisms operate independently within the host. Such assumptions are considered biologically plausible and defensible and can be used to derive a family of dose-response functions that include the beta-Poisson.

The following data were used to estimate the annual number of symptomatic *E. coli* O157:H7 infections due to ground beef:

- surveillance data from the FoodNet surveillance program,
- data from epidemiologic studies of sporadic cases and outbreaks of *E. coli* O157:H7 infection and other public health studies and surveys,

- data from human clinical trials using *Shigella dysenteriae* type I and enteropathogenic *E. coli* (EPEC), and
- dose-reconstruction data from a large outbreak of *E.* coli O157:H7 in the Pacific Northwest.

Estimates of the baseline annual number of *E. coli* O157:H7 cases from all causes were derived from surveillance data. This baseline number of cases was adjusted upward to account for recognized causes of underreporting, such as ill persons not seeking medical care, false negative test results, and laboratories not culturing fecal samples for *E. coli* O157:H7, resulting in an estimate of the total annual number of symptomatic *E. coli* O157:H7 cases in the United States. The estimated total annual number of cases was then multiplied by estimates of the proportion of cases due to ground beef exposure to arrive at the annual number of cases of symptomatic *E.* coli O157:H7 cases due to ground beef exposure. This estimated number of cases due to ground beef exposure was then combined with the estimated number of contaminated ground beef servings from the exposure assessment to complete the *E. coli* O157:H7 dose-response function (Figure 9).

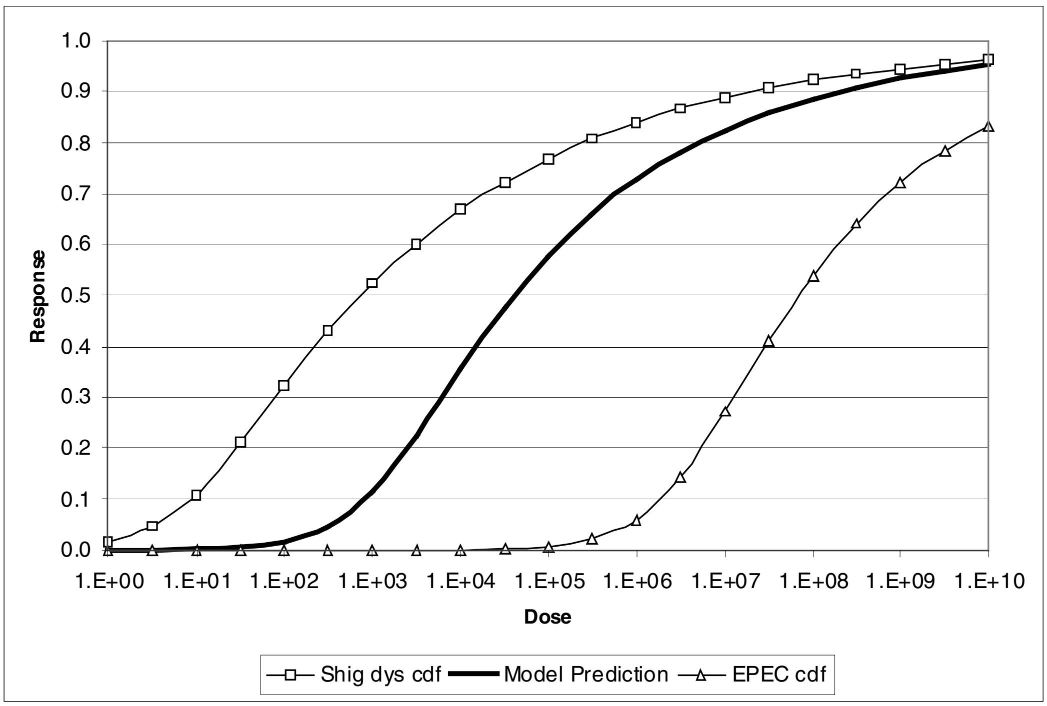


FIGURE 9. The median dose-response curve for *E. coli* O157:H7 bounded by upper and lower dose-response curves derived from *E. coli* O157:H7 surrogate pathogens, *Shigella dysenteriae* (Shig dys cumulative distribution function [cdf]) and enteropathogenic *E. coli* (EPEC cdf), respectively.

No human clinical trial data are available for *E. coli* O157:H7, but they are available for other foodborne pathogens that could be used as surrogates. Two surrogate dose-response models were used to bound the uncertainty on the *E. coli* O157:H7 dose-response curve. Data from experimental exposure of persons to *S. dysenteriae* were used to estimate the upper bound, based on the assumption that *E. coli* O157:H7 is unlikely to be more pathogenic than this invasive *Shigella* species. Data from experimental exposure of persons to four EPEC strains were combined and used to estimate the lower bound, based on the assumption that *E. coli* O157:H7 is unlikely to be less pathogenic than the EPEC strains.

The output of these beta-Poisson models is the estimated proportion of persons expected to experience illness given a dose. The proportion of persons expected to fall ill at a given dose multiplied by the number of servings containing that dose, as estimated by the exposure assessment portion of the model, results in an estimate of the number of persons expected to become ill during a year.

The model estimates that a median of 94,000 cases of symptomatic *E. coli* O157:H7 infection occur annually in the United States, as a result of all exposures. Of these, approximately 20% of the cases were characterized by bloody diarrhea and about 50% of these cases sought medical care. Of those cases that sought medical care, an estimated 21% were hospitalized. Of the hospitalized patients, the model estimates that a median of 23% of these patients developed HUS or TTP and that 11% of these HUS patients died.

When considering only cases due to contaminated ground beef, the model estimates a median of 19,000 cases of symptomatic *E. coli* O157:H7 infection annually in the United States. Of these, 3,800 cases are expected to experience bloody diarrhea, and about 1,800 of these cases would seek medical care. Of the cases seeking medical care, the model estimates that 400 cases will be hospitalized. About 90 of the hospitalized cases would be expected to develop HUS or TTP, and 10 of the HUS/TTP patients would die.

RISK CHARACTERIZATION

Risk characterization integrates the results of the exposure assessment with the results of hazard characterization to estimate the risk of illness from *E. coli* O157:H7 in ground beef. Risk characterization considers several risk estimates, including the risk of illness from *E. coli* O157:H7 in ground beef for a typical individual, a community in a simulated outbreak, and the U.S. population. Risk characterization also includes an analysis to identify variables that influence the occurrence and extent of *E. coli* O157:H7 contamination in ground beef and the subsequent risk of illness. These variables represent important areas where mitigation strategies could potentially be applied to reduce the risk of illness from *E. coli* O157:H7 in ground beef.

Population Risk of Illness

The risk of becoming ill from *E. coli* O157:H7 in ground beef depends both on the probability of being exposed to a specific number of *E. coli* O157:H7 in a ground beef serving <u>and</u> the probability of illness given that exposure. The United States population risk of illness is nearly 1 illness in each 1 million (9.6×10^{-7}) servings of ground beef consumed. This annual U.S. population risk estimate is based on the central tendencies (median) of both the exposure distribution and dose-response functions. Uncertainty about this risk ranges from about 1 illness in every 3 million ground beef servings at the 5th percentile to about 2 illnesses in every 1 million ground beef servings at the 95th percentile. The U.S. population risk of illness from *E. coli* O157:H7 in ground beef is driven more by the number of contaminated servings than by the amount of contamination in a serving.

Given approximately 18.2 billion servings of ground beef consumed per year, the risk assessment predicts about 17,500 cases of *E. coli* O157:H7 illness per year (50th percentile). The median number of cases per year predicted from public health surveillance data in hazard characterization is approximately 19,000. Because the uncertainty distributions describing the exposure distribution (e.g., the probability of the number of *E. coli* O157:H7 in a ground beef serving [dose]) and dose-response function (e.g., the probability of illness given a dose of *E. coli* O157:H7 in ground beef servings) are not symmetrical, these two estimates of illness do not precisely correspond.

Risk of Hospitalization, HUS, and Death

Based on a U.S. population risk of illness from *E. coli* O157:H7-contaminated ground beef, the probability of severe illnesses can be estimated using the information developed in the hazard characterization. The population risk of being hospitalized but recovering is 2.0×10^{-8} per ground beef serving; the population risk of developing HUS but recovering is 4.2×10^{-9} per ground beef serving; and the population risk of death from *E. coli* O157:H7 in ground beef is 5.9×10^{-10} per serving.

Season and Age

The risk of illness from *E. coli* O157:H7 in ground beef can vary among subpopulations of the U.S. based on differences in host susceptibility or differences in exposure. The *E. coli* O157:H7 risk assessment considered variability in seasonal *E. coli* O157:H7 contamination of ground beef servings, age of the consumer, and location of the meal (i.e., home versus "away from home").

The risk of illness from *E. coli* O157:H7 in ground beef was about three times higher during June to September than during the rest of the year. Specifically, about 1 in every 600,000 ground beef servings (1.7×10^{-6}) consumed during June through September is predicted to result in illness, while about 1 in every 1.6 million servings (6.0×10^{-7}) consumed during October to May is expected to result in illness.

The risk of illness from *E. coli* O157:H7 in ground beef was about 2.5 times higher for children aged 0 to 5 than for the rest of the population. Children under 5 years of age are less exposed to *E. coli* O157:H7 in ground beef because this age group consumes fewer servings (7% of all ground beef servings consumed annually in the United States) and smaller serving sizes (average of 44 grams compared with 90 grams for the rest of the population). Surveillance data indicate that this age group is more susceptible to illness from *E. coli* O157:H7. Applying the upper bound of the *E. coli* O157:H7 dose-response function—the *Shigella dysenteriae* dose-response curve—to these children's exposures predicts that 15% of all illnesses from *E. coli* O157:H7 in ground beef occur in this age group.

Sensitivity Analysis

The *E. coli* O157:H7 risk assessment included a sensitivity analysis to identify factors that most influence the occurrence or extent of *E. coli* O157:H7 contamination in ground beef and the subsequent risk of illness. One technique involved analyzing how changes in model inputs were related to changes in model outputs (correlation analysis). Another technique involved making specified changes to model inputs and observing the effect on model outputs (dependency analysis).

The occurrence and extent of *E. coli* O157:H7 contamination in beef trim and subsequent grinder loads was most influenced by

- feedlot and within-feedlot prevalence,
- probability of carcass contamination following dehiding,
- amount of carcass contaminated,

- effectiveness of decontamination procedures, and
- carcass chilling.

The effect of these factors on the occurrence and extent of *E. coli* O157:H7 in beef trim and grinder loads varied by season and type of cattle (steer/heifer or cow/bull). For example, the amount of carcass contaminated was correlated (coefficient: 0.33) with the amount of *E. coli* O157:H7 in steer/heifer combo bins during the high prevalence season (June to September) but not with the number of *E. coli* O157:H7-contaminated combo bins during this season. In contrast, the amount of carcass contaminated was not correlated (i.e., coefficient <0.30) with either the number of *E. coli* O157:H7 organisms in cow/bull combo bins or the number of *E. coli* O157:H7-contaminated cow/bull combo bins for the low prevalence season (October to May).

The importance of these factors varied by season (June to September or October to May). Although some factors influenced the occurrence of *E. coli* O157:H7 in combo bins, grinder loads, or ground beef servings, others were more important in influencing the extent of *E. coli* O157:H7 contamination in these units. Because the overall U.S. population risk of illness from *E. coli* O157:H7 in ground beef is influenced more by the number of contaminated ground beef servings than by the amount of *E. coli* O157:H7 in a contaminated ground beef serving, these differences among identified influential factors may be important.

The occurrence and extent of *E. coli* O157:H7 contamination in cooked ground beef servings was understandably influenced by the occurrence and extent of *E. coli* O157:H7 contamination in beef trim and subsequent grinder loads. It was also greatly influenced by

- the proportion of ground beef that is frozen,
- the maximum population density of *E. coli* O157:H7 in ground beef,
- storage temperatures, and
- cooking.

Perhaps the most important finding was that consumers can still be exposed to *E. coli* O157:H7 in ground beef even if servings are fully cooked (i.e., 5 log reduction) due to extensive growth of *E. coli* O157:H7 through improper storage and handling.[1] Both proper storage and adequate cooking are necessary to prevent illness from *E. coli* O157:H7 in ground beef.

RESEARCH NEEDS

The baseline risk assessment described in this document uses available data to model the occurrence of *E. coli* O157:H7 in cattle on the farm to the prevalence of contaminated servings of cooked ground beef. This risk assessment is structured to allow incorporation of additional data as they become available. The determination of which data would be most beneficial is based on areas identified as important and areas for which there is limited information. Several areas of food safety research would strengthen the certainty of estimates from this risk assessment, including

- additional information on *E. coli* O157:H7 contamination on carcasses following dehiding;
- data on the effect of carcass chilling on increases or decreases in *E. coli* O157:H7 organisms;

[1] The maximum population density for of *E. coli* O157:H7 in ground beef servings can vary depending on food matrix characteristics (e.g., pH, water activity) and competitive microflora. The most likely maximum population density for *E. coli* O157:H7 in ground beef is between 5 and 10 logs. The importance of proper storage versus adequate cooking depends on the maximum population density.

- predictive microbiological data on the increase and decrease in the number of *E. coli* O157:H7 organisms in ground beef under various storage and preparation conditions along with estimates of the frequencies of occurrence of these storage and preparation conditions;
- information on the maximum density of *E. coli* O157:H7 organisms in ground beef servings as a result of matrix effects, competitive microflora in ground beef, and environmental conditions (e.g., pH, water activity); and
- data on the retail (hotels, restaurants, and institutions [HRI]) and consumer storage, cooking, and consumption (frequency and serving size) patterns by type of ground beef meal (e.g., grilled hamburger or baked meat loaf) and season.

SUMMARY

The baseline risk assessment described in this document models the occurrence of *E. coli* O157:H7 in cattle on the farm to the occurrence and extent of contaminated servings of cooked ground beef. The exposure assessment concludes that feedlot cattle (steers and heifers) have a higher prevalence of *E. coli* O157:H7 infection than culled breeding cattle (cows and bulls). Although only a fraction of infected live cattle result in contaminated carcasses, up to thousands of pounds of meat trim from these carcasses are combined in the grinding process. Consequently, although the concentration of *E. coli* O157:H7 in these grinder loads may be quite low, the proportion of grinder loads that contain one or more *E. coli* O157:H7 organism is expected to be high. The effects of storage, holding times, chilling, and cooking were included throughout the model to account for organism growth or decline. The median probability of illness for the general U.S. population due to *E. coli* O157:H7 from a serving of ground beef is estimated to be 9.6×10^{-07} or about 1 illness in every 1 million servings. For children aged 0 to 5, the risk is estimated to be 2.4×10^{-06} or about 2.5 illnesses in every 1 million consumed ground beef servings.

Some cautions on the appropriate use of this risk assessment should be noted. First, it is never possible to model reality in its entirety. The conclusions in this risk assessment are based on current data and scientific assumptions. Fortunately, risk assessment is an iterative process, and additional data can be incorporated into the model as they become available. Second, the risk assessment results provide only part of the information needed by decision makers and regulators. The risk assessment does not address such issues as cost, feasibility, or effectiveness of possible interventions. These analyses are necessary before deciding which of many possible policies should be implemented regarding *E. coli* O157:H7 in ground beef.

Finally, FSIS is releasing this report documenting the baseline risk assessment on *E. coli* O157:H7 in ground beef for public comment and scientific peer review by the National Academy of Sciences. Thus, the risk assessment is a “work in progress.” In addition, FSIS invites public input to further strengthen this farm-to-table baseline risk assessment for *E. coli* O157:H7 in ground beef.