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Introduction

Escherichia coli O157:H7 was first recognized as a foodborne pathogen with major public health consequences in 1982, when it was associated with two outbreaks of bloody diarrhea in Oregon and Michigan (Riley et al. 1983). Between 1982 and 1998, over 4,400 cases of human illness resulted from 203 outbreaks that involved exposure to *E. coli* O157:H7 (CDC unpublished data). Of these cases, 968 (22%) were hospitalized, 228 (5%) progressed to hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP), and 28 (0.6%) died. Surveillance data indicate that the highest incidence of illness from *E. coli* O157:H7 occurs in children under 5 years of age (CDC 1999a).

Epidemiological evidence indicates that ground beef is the primary source of human exposure to *E. coli* O157:H7. Between 1982 and 1993, ground beef was identified as the transmission source in 54% of *E. coli* O157:H7 outbreaks (Griffin 1995). Of the *E. coli* O157:H7 outbreaks reported between 1993 and 1998, most (72%) were foodborne. Of the foods implicated in these outbreaks, beef was the most common (45%) source. When specified, 90% of the time the beef product was ground (CDC 1999b; CDC 2000; CDC 2001). Studies of sporadic cases of *E. coli* O157:H7 illness also identified ground beef as the primary source of human exposure (MacDonald et al. 1988; Le Saux et al. 1993; Mead et al. 1997; Slutsker et al. 1998; Kassenborg et al. 2001).

As the public health regulatory agency responsible for ensuring that meat and poultry products are properly labeled, wholesome, and safe, the Food Safety and Inspection Service (FSIS) took the following additional steps to prevent the occurrence of *E. coli* O157:H7 in ground beef sold to the U.S. public:

- In August 1994, FSIS declared that ground beef containing *E. coli* O157:H7 is adulterated under the Federal Meat Inspection Act unless further processed in a manner that destroys this pathogen.[1]
- 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.[2] The initial testing program was established and designed to test approximately 5,000 raw ground beef samples per year, 50% from federally inspected plants and 50% from retail stores.
- In 1998, because of the low concentrations of *E. coli* O157:H7 recovered from samples of frozen ground beef patties identified in 1993 and 1997 *E. coli* O157:H7 outbreaks in Colorado[3,4], FSIS increased the microbiological testing sample size from 25 grams to 325 grams. The increased sample sizes were necessary to improve detection of *E. coli* O157:H7 in raw ground beef sold to consumers.
- In August 1998, FSIS initiated a consumer education campaign encouraging use of food thermometers to ensure that ground beef is cooked to an internal temperature of at least 160°F (FSIS 1998).
- In September 1999, FSIS introduced a more sensitive laboratory test for *E. coli* O157:H7 that used an additional selective capture step based on immunomagnetic separation (FSIS 1999).[5]
- In February 1999, FSIS proposed to permit the use of ionizing radiation for treating refrigerated or frozen uncooked meat food products to reduce the concentration of foodborne pathogens, including *E. coli* O157:H7 (*Federal Register*, Volume 64, pages 9089-9105).[6]

PURPOSE OF THE *E. COLI* O157:H7 RISK ASSESSMENT

In addition to setting new standards and improving microbiological testing for *E. coli* O157:H7 in ground beef, on August 18, 1998, FSIS announced plans to conduct a farm-to-table risk assessment (*Federal Register*, Volume 63, page 44232). The result was the risk assessment documented in this report. The overall goals of this risk assessment are to

- provide a comprehensive evaluation of the risk of illness from *E. coli* O157:H7 in ground beef based on currently available scientific data,
- estimate the likelihood of human morbidity and mortality associated with specific numbers of *E. coli* O157:H7 in ground beef servings,

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[1]If a ground beef sample is confirmed positive, FSIS inspectors will condemn the sampled lot unless it is fully cooked (in accordance with 9 CFR 318.23) or processed in a way that would eliminate the pathogen (FSIS Directive 10,010.1). FSIS Directive 8080.1 Rev. 2 (11-3-92) outlines the basic procedures for recall of an inspected meat or poultry product.

[2]In December 1994, the agency won a court challenge of the policy and the testing program. The testing program operated under FSIS Notice 50-94, issued on December 23, 1994, until the agency issued FSIS Directive 10,010.1 on February 1, 1998.

[3]The most probable number (MPN) of *E. coli* O157:H7 recovered from six samples from the 1993 outbreak ranged from 30 to 1,500 organisms per 100 grams (Johnson et al. 1995; Marks et al. 1998).

[4]Tuttle et al. (1999) reported an MPN of 67 *E. coli* O157:H7 organisms per uncooked patty.

[5]Consequently, recent increases in the reported frequency of *E. coli* O157:H7 detection reflect, at least in part, increased sample sizes and the use of a more sensitive test for detection of *E. coli* O157:H7.

[6]The Final Rule for the Irradiation of Meat Food Products was published on December 23, 1999 (*Federal Register*, Volume 64, pages 72149-72166).

- estimate the occurrence and extent of *E. coli* O157:H7 contamination at points along the farm-to-table continuum,
- provide a tool for analyzing how to most effectively mitigate the risk of illness from *E. coli* O157:H7 in ground beef (one that is useful for Pathogen Reduction and Hazard Analysis and Critical Control Point applications),
- identify future food safety research needs, and
- assist FSIS in the review and refinement of its integrated risk reduction strategy for *E. coli* O157:H7 in ground beef.

STRUCTURE OF THE *E. COLI* O157:H7 RISK ASSESSMENT

The *E. coli* O157:H7 risk assessment follows the generally accepted structure for microbiological risk assessments: hazard identification, exposure assessment, hazard characterization, and risk characterization. *Hazard identification* serves to identify biological agents that may be present in a particular food or groups of food and are capable of causing adverse health effects. *Exposure assessment* is the quantitative evaluation of the likely intake of biological agents via food, as well as exposures from other sources, if relevant. *Hazard characterization* is the quantitative evaluation of the adverse health effects associated with the hazard. This step includes a *dose-response assessment* that determines the relationship between the magnitude of exposure dose to a biological agent and the frequency of associated adverse health effects (response). Finally, *risk characterization* is the process of determining the quantitative estimation, including attendant uncertainties, of the frequency of occurrence and severity of adverse health effects in a given population based on the hazard identification, exposure assessment, and hazard characterization.

The *E. coli* O157:H7 risk assessment provides numerical expressions of risk and an indication of the attendant uncertainties. Scientific data are the foundation of this risk assessment. This risk assessment includes data available through July 2001. By integrating scientific data through a structured process, the *E. coli* O157:H7 risk assessment provides information that links policy and science. A structured process is essential to risk assessment because describing risk rarely involves the certainty of direct, measurable observations relevant to human health; instead, it involves statistical estimation and prediction, as well as transparent expression of uncertainty.

The *E. coli* O157:H7 risk assessment is a *baseline* risk assessment in that it reflects, to the extent practicable, a full range of current practices, behaviors, and conditions in the farm-to-table continuum (production, slaughter, processing, transportation, storage, preparation, and consumption) (Figure 1-1). This risk assessment is intended to assist FSIS risk managers in identifying potential areas along the farm-to-table continuum to control *E. coli* O157:H7. Using this baseline risk assessment, risk managers will identify a set of feasible control options to analyze. Use of the risk assessment to evaluate different control strategies is known as conducting a scenario analysis. Subsequent scenario analyses using the *E. coli* O157:H7 risk assessment will provide FSIS decision makers with information concerning the efficacy of alternative mitigation strategies and a tool to evaluate these strategies to decrease the number of human illnesses resulting from *E. coli* O157:H7 in ground beef. A sensitivity analysis is included with this baseline risk assessment to provide FSIS risk managers with information on (1) the potential areas to consider in reviewing and refining mitigation strategies and (2) the most important data gaps and key uncertainties for future data collection and research.

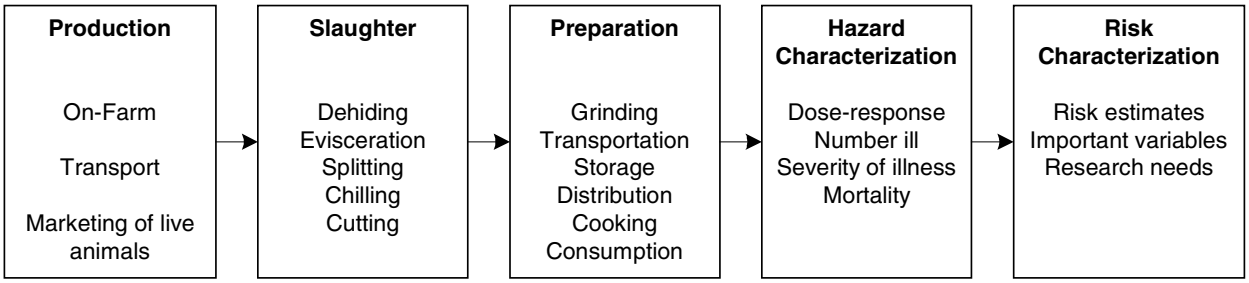

FIGURE 1-1 Risk assessment structure for *E. coli* O157:H7 in ground beef.

SCOPE OF THE *E. COLI* O157:H7 RISK ASSESSMENT

As announced in the *Federal Register* (Volume 63, page 44232), the scope of this risk assessment is confined to ground beef products, based on an analysis of available epidemiologic data (Mead et al. 1999).[7] At the broadest level of aggregation, the scope of the assessment includes two classes of product: (1) products consisting of 100% ground beef and (2) other products containing ground beef. Due to the lack of available data, the scope of the assessment does not distinguish ground beef products (i.e., hamburger or meat patties [as defined in 9 CFR 319.15] that also contain comminuted beef processed by means other than grinding [e.g., mechanical separation and partial defatting]).

A number of factors were considered in assessing the risk of illness from *E. coli* O157:H7 in ground beef, including (1) the number of illnesses and severity of these illnesses caused by *E. coli* O157:H in ground beef; (2) the likelihood of *E. coli* O157:H7 (hazard) being present in a ground beef serving (exposure); (3) the likelihood that exposure to a given number of *E. coli* O157:H7 in a ground beef serving will cause illness (dose-response); (4) the probability of illness from *E. coli* O157:H7 in ground beef servings (risk); (5) consideration of the risk of illness from several perspectives (individual, community, and population); (6) the variation in population exposure (e.g., seasonal exposure) and response (e.g., by age category, children under 5 years of age) (variability); (7) identification of production, slaughter, and preparation practices and conditions that influence the likelihood of exposure to *E. coli* O157:H7 in ground beef or the subsequent risk of illness (sensitivity analysis); and (8) limitations in the current state of knowledge (uncertainty).

Beyond the scope of the present risk assessment are nonintact cuts of beef in which *E. coli* O157:H7 may be introduced below the surface of the whole cut. This may occur by means of injection, mechanical tenderizing, or reconstruction (e.g., beef that has been scored to incorporate a marinade or that has been cubed and mechanically tenderized, and restructured beef products such as gyros). Contamination may also occur in a comminution process such as chopping, flaking, or mincing (e.g., fresh veal sausage and fabricated beefsteak) the whole cut. If, however, such a comminuted beef product is combined with ground beef in the formulation of

[7]On January 19, 1999, FSIS announced that, in addition to ground beef, beef trimmings defined as intact are considered adulterated if they contain *E. coli* O157:H7. FSIS said resulting processed products from the contaminated trimmings are considered adulterated and must not be distributed until they have been processed into a ready-to-eat product (i.e., a food product that may be consumed safely without any further cooking or other preparation) (*Federal Register*, Volume 64, pages 2803-2805). For a discussion of more recent developments regarding FSIS policy for beef products contaminated with *E. coli* O157:H7, see the *Federal Register*, Volume 65, pages 6881-6886.

a food product, it is included in the scope of this risk assessment. FSIS plans to incorporate nonintact beef products that are beyond the scope of the present assessment in future iterations of this risk assessment model.

This risk assessment also does not explicitly model imported beef as distinct from domestic beef. Approximately 15% of the fresh, chilled, and frozen beef and veal consumed in the United States originates from outside the country, and 90% of such imports are from Australia, New Zealand, and Canada (APHIS:VS:CEAH 1994). Specific data regarding the prevalence of *E. coli* O157:H7 in beef imported from various countries are lacking, and published surveillance data from the three major exporters to the U.S. are variable. However, evidence does indicate that *E. coli* O157:H7 occurs in Australian, New Zealand, and Canadian cattle and humans (Robins–Browne et al. 1998; New Zealand Public Health Report 2000; Spika et al. 1998). In general, this evidence does not suggest that the prevalence of *E. coli* O157:H7 is dramatically greater in those countries than in the United States. Therefore, the assumption of equivalence in contamination of imported and domestic product is likely conservative in the model.

As announced in the *Federal Register* (Volume 63, page 44232), the scope of the analysis does not extend beyond beef as a vehicle of infection. A common concern expressed in public comments submitted to the docket and during the October 28, 1998, public meeting was that the proposed scope of the analysis was limited to foods containing ground beef and thereby omitted other important sources of *E. coli* O157:H7 infection, such as vegetables, produce, juice, water, and person-to-person transmission. However, FSIS determined that to make the analysis tractable, and in light of resource and time constraints, the scope of the assessment would necessarily have to be fixed or defined. Furthermore, the Centers for Disease Control and Prevention (CDC) recently estimated the total disease burden of *E. coli* O157:H7 from all products based on epidemiologic surveillance data (Mead et al. 1999). Consequently, there has been no attempt to quantitatively model cross-contamination or other sources of *E. coli* O157:H7 (e.g., nonbeef food products, water, and fomites). Similarly, there are currently no plans to quantitatively model secondary infections resulting from person-to-person contact. The delimited scope of the analysis has been taken into account in comparing the results predicted by the baseline risk assessment model with estimates of illnesses derived from observed epidemiologic data (Mead et al. 1999).

An increased seasonal incidence of *E. coli* O157:H7 infections in U.S. cattle and human populations has been previously demonstrated in the warm months (i.e., June to September) (Hancock et al. 1997a, 1997b; Griffin 1998). Seasonal patterns are also demonstrated for Canada (Van Donkersgoed et al. 1997) and likely occur in other countries. Seasonal effects were modeled in this risk assessment using data on the prevalence of *E. coli* O157:H7 within infected cattle herds. To improve the certainty of modeling seasonal variability for the risk of illness from *E. coli* O157:H7, additional data are needed on changes in the occurrence of *E. coli* O157:H7 in raw ground beef across seasons; changes in slaughter and processing practices by season; and changes in storage, handling, preparation, and consumption practices by season.

RESULTS OF THE *E. COLI* O157:H7 RISK ASSESSMENT

The risk assessment model yields intermediate and final outputs in the form of distributions that characterize the variability and uncertainty in estimates of a variety of risk assessment endpoints or human illnesses (Table 1-1). For hazard identification, outputs include information on the

TABLE 1-1 Outputs of the *E. coli* O157:H7 Risk Assessment

Component	Module	Outputs
Hazard Identification		Epidemiological information on human morbidity and mortality due to *E. coli* O157:H7
		Microbiological information on the pathogenesis of *E. coli* O157:H7 compared with other *E. coli* strains
		Information on the source and transmission of *E. coli* O157:H7
		Information on the environmental conditions that influence survival and growth (predictive microbiology) of *E. coli* O157:H7
Exposure Assessment	Production	Herd and within-herd prevalence rates for infected live cattle prior to slaughter for ground beef
	Slaughter	Prevalence of contaminated carcasses
		Number of *E. coli* O157:H7 organisms on contaminated carcasses
		Prevalence of contaminated combo bins of trim
		Number of *E. coli* O157:H7 organisms in combo bins of contaminated trim
	Preparation	Prevalence of contaminated grinder loads of ground product
		Number of *E. coli* O157:H7 organisms in contaminated grinder loads of ground product
		Prevalence of contaminated cooked ground beef servings
		Number of *E. coli* O157:H7 organisms in contaminated cooked ground beef servings
Hazard Characterization		Annual number of *E. coli* O157:H7 illnesses associated with cooked ground beef consumption
		Annual number of hospitalizations due to *E. coli* O157:H7 in cooked ground beef
		Annual number of cases of HUS/TTP due to *E. coli* O157:H7 in cooked ground beef
		Annual number of deaths due to *E. coli* O157:H7 in cooked ground beef
Risk Characterization		Annual risk of illness from *E. coli* O157:H7 in cooked ground beef
		Annual risk of illness from *E. coli* O157:H7 in cooked ground beef by seasonal exposure and age of the consumer
		Identification of important variables that influence the risk of illness from *E. coli* O157:H7 in ground beef
		Identification of important food safety research areas

epidemiology, transmission, ecology, and pathogenesis of *E. coli* O157:H7. Exposure assessment outputs include the prevalence of *E. coli* O157:H7-infected cattle and the occurrence and number of *E. coli* O157:H7 in combo bins of beef trim, grinder loads of ground beef, and cooked ground beef servings. Primary outputs of the hazard characterization are the number and severity of human illnesses associated with a specific number of *E. coli* O157:H7 organisms per serving (dose) and a derived dose-response function. Final outputs of the risk assessment are provided in the risk characterization and include (1) estimates of the risk of illness from *E. coli* O157:H7-contaminated ground beef for individuals, communities, and the U.S. population; (2) estimates of the U.S. population risk by season (June to September and May to October) and age (i.e., children under 5 years of age); (3) estimates of variables that are most responsible for influencing the likelihood of exposure to *E. coli* O157:H7 in ground beef servings and subsequent risk of illness; and (4) identification of important food safety research needs.

HISTORY OF THE *E. COLI* O157:H7 RISK ASSESSMENT PROJECT

Work on the *E. coli* O157:H7 baseline risk assessment in ground beef was initiated in March 1998 when the Interagency Food Risk Assessment Group, convened by the Office of Risk Assessment and Cost Benefit Analysis, formed an informal resource group. This interagency group identified resources and available data to initiate this risk assessment and organized a public meeting to solicit comment and input at an early stage of this project about the

- scope of the risk assessment,
- analytical framework to be used in conducting the risk assessment,
- scientific evidence acquired by the risk assessment team to date, and
- existing data gaps identified by the risk assessment team.

The public meeting was held on October 28, 1998, in Arlington, Virginia, and was attended by more than 60 individuals. At this meeting, FSIS released the "Preliminary Pathways and Data for a Risk Assessment of *E. coli* O157:H7 in Beef." That document summarized the currently available data and potential foodborne exposure pathways under consideration for this risk assessment.

Comments and additional data identified during the public meeting or submitted to the docket in response to the August 18, 1998, *Federal Register* Notice were evaluated for inclusion in the development of the baseline risk assessment. A complete transcript of the public meeting and all public submissions regarding the risk assessment are on file in the FSIS docket (Docket Number 98-037N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, 300 12th Street, SW, Washington, DC 20250-3700).

An interim draft of the *E. coli* O157:H7 baseline risk assessment was presented for public and scientific input at several meetings, including the 1998 Annual Meeting of the Society for Risk Analysis (SRA); the 1999 Annual Meeting of the International Association of Milk, Food and Environmental Sanitarians; a week-long interagency workshop on microbial risk held in April 1999; the 1999 Annual Meeting of the SRA; and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). A revised interim draft *E. coli* O157:H7 baseline risk assessment report incorporating public and scientific input from these meetings was developed. This interim draft report was presented to the public on February 29, 2000, to discuss FSIS policy regarding *E. coli* O157:H7. The presentation is available at http://www.fsis.usda.gov/OPHS/ecolrisk.

Based on input from these meetings, this risk assessment has been substantially revised and strengthened. FSIS is releasing this draft 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. This risk assessment is a "work in progress." In finalizing the baseline *E. coli* O157:H7 risk assessment, the agency will consider the comments of the National Academy of Sciences and public comments submitted to the FSIS docket within 60 days of the release date of this report.

ORGANIZATION OF THE REMAINDER OF THIS REPORT

This risk assessment report is divided into five chapters. Chapter 2 (hazard identification) provides information on the epidemiology, pathogenesis, transmission, and ecology of *E. coli* O157:H7. Chapter 3 (exposure assessment) describes the occurrence and number of *E. coli* O157:H7 organisms from farm to table. Chapter 4 (hazard characterization) discusses the derivation of a dose-response function for *E. coli* O157:H7. Chapter 5 (risk characterization) integrates the results of the previous chapters to provide estimates of the risk of illness from *E. coli* O157:H7 in ground beef. Risk characterization also includes a sensitivity analysis, identifying variables along the farm-to-table continuum that greatly influence the risk of illness from *E. coli* O157:H7. Variables that are identified as important but for which there is limited information are listed as areas for further research in Chapter 5.

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