

**INTERPRETIVE SUMMARY**  
**COMPARATIVE RISK ASSESSMENT FOR INTACT (NON-TENDERIZED) AND NON-INTACT (TENDERIZED) BEEF**  
**March 18, 2002**

**1. RISK MANAGEMENT REQUESTS AND OBJECTIVES**

In October 2001, the Office of Policy, Program Evaluation and Development (OPPDE) requested the following types of risk assessments to support policy decision-making regarding *E. coli* O157:H7 in non-intact beef:

- (1) a farm-to-table risk assessment to evaluate the effectiveness of interventions in reducing the occurrence and extent of *E. coli* O157:H7 contamination on carcasses and reduce the subsequent risk of illness; and
- (2) a comparative risk assessment to evaluate the risk of illness per serving from intact versus non-intact (e.g., tenderized) beef steaks and roasts prepared using traditional cooking practices (grilling, broiling, and frying).

The requested farm-to-table risk assessment for non-intact (tenderized) beef could not be developed because of the lack of sufficient data on the prevalence and level of *E. coli* O157:H7 on specific locations of the carcass (see the *Risk Assessment Plan for Non-Intact Beef*; FSIS 2001). There was, however, sufficient data to assess the risk of illness from non-intact (tenderized) beef compared to intact (non-tenderized) beef.

The comparative risk assessment, including modeling approach, data inputs and underlying assumptions, as well as the resulting risk estimates are summarized below. For additional technical detail, see the *Technical Report: Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef* (FSIS, March 2002).

**2. PUBLIC HEALTH REGULATORY CONTEXT**

**2.1. Public Health Background**

*E. 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. 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 (Mead 1999).

While epidemiological evidence indicates that ground beef is the primary foodborne source of exposure to *E. coli* O157:H7, a recent study of the survival of *E. coli* O157:H7 in tenderized beef under customary cooking practices suggests that these sources of non-intact beef may also pose a public health risk (Sporing 1999, KSU 2001). Non-intact beef has also been implicated as the source of *E. coli* O157:H7-related illnesses in recent foodborne outbreaks in the U.S. and Canada (Michigan Department of Community Health 2000,

Wisconsin Department of Health and Family Services 2000, and Health Canada 2002).<sup>1</sup> In two of these outbreaks, undercooked non-intact beef (e.g., beef tournedos and beef roasts) was implicated as the most likely vehicle for *E. coli* O157:H7 (Michigan Department of Community Health 2000, Health Canada 2002). In the third outbreak, illnesses may have resulted from the consumption of food that was cross-contaminated with *E. coli* O157:H7 from non-intact beef (Wisconsin Department of Health and Family Services 2000).

## 2.2. Regulatory Background

To protect public health, FSIS declared raw non-intact beef, including ground beef, adulterated if it contains *E. coli* O157:H7. This policy is based on the premise that *E. coli* O157:H7, an extremely virulent organism, may survive after cooking non-intact beef products and cause serious illness in consumers. In contrast, FSIS does not consider intact beef containing *E. coli* O157:H7 to be adulterated because it is assumed that any *E. coli* O157:H7 on the surface of these products would be destroyed during cooking.

The regulatory history for *E. coli* O157:H7 in beef is provided below:

*Ground beef.* In 1994, FSIS notified the public that raw ground beef contaminated with *E. coli* O157:H7 is adulterated under the Federal Meat Inspection Act (FMIA) unless the ground beef is further processed to destroy this pathogen. Also in 1994, FSIS began sampling and testing ground beef for *E. coli* O157:H7.

*Non-intact beef.* On January 19, 1999, FSIS published a Federal Register notice explaining that all raw non-intact beef products (e.g., those that have been mechanically tenderized by needling or cubing), in addition to ground beef, that are found to be contaminated with *E. coli* O157:H7 must be processed into ready-to-eat product, or they would be deemed to be adulterated.

*Intact beef.* The January 1999 notice also explained that if intact cuts of beef that are to be further processed into non-intact product prior to distribution for consumption (e.g., manufacturing trimmings) are found to be contaminated with *E. coli* O157:H7, they must be processed into ready-to-eat product, or they would be deemed to be adulterated. FSIS would also consider it acceptable to irradiate these products prior to distribution for consumption, if they are found contaminated with *E. coli* O157:H7.

*Justification of the 1999 policy.* FSIS explained that: (1) *E. coli* O157:H7 is an extremely virulent organism; and (2) *E. coli* O157:H7 may survive cooking in non-intact beef and cause illness among consumers. FSIS explained that pathogens, including *E. coli* O157:H7, may be introduced below the surfaces of non-intact products (e.g., tenderized beef) as the result of the processes by which they are made. As a result, customary cooking of these products may not be adequate to kill the pathogens.<sup>2</sup> In contrast, the meat interior of intact products remains essentially protected from pathogens migrating below the exterior. Consequently, customary cooking of intact products will destroy any *E. coli* O157:H7.

---

<sup>1</sup> These *E. coli* O157:H7 outbreaks did not provide sufficient quantitative data for use in this risk assessment.

<sup>2</sup> FSIS believes that there is ample anecdotal evidence that consumers frequently eat blade tenderized meat, particularly steaks, cooked “rare” or medium.” The Agency thought that this method of preparation would be insufficient to destroy *E. coli* O157:H7 in the interior of the meat and, as a result, may render the product injurious to health.

### 3. SCIENTIFIC GUIDANCE

A subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was asked to answer several questions with regard to the potential public health risk posed by *E. coli* O157:H7 in blade-tenderized, non-intact beef (e.g., steaks and roasts) (NACMCF 2002). The following questions were addressed:

- Q1: Do non-intact, blade tenderized beef steaks present a greater risk to the consumer from *E. coli* O157:H7 compared to intact beef steaks if prepared similarly to intact beef steaks?
- Q2: Do non-intact, blade tenderized beef roasts present a greater risk to the consumer from *E. coli* O157:H7 compared to intact beef roasts if prepared similarly to intact beef roasts?
- Q3: Is the available information on non-intact products adequate to answer questions 2 and 3? If not, are there other reasons to conclude that the translocation of *E. coli* O157:H7 that occurs with the blade tenderization or similar processes renders traditional cooking (consider the traditional cooking process for these products to be very rare or rare) of these products inadequate to kill the pathogen?
- Q4: Does the available scientific evidence support the need for a labeling requirement to distinguish between intact and non-intact products in order to enhance public health protection?

NACMCF considered several sources of information in addressing these questions, including epidemiologic data, FSIS microbiological baseline data, the Kansas State University study (Spring 1999), data on the predictive microbiology of *E. coli* O157:H7 under various cooking conditions, consumer cooking behavior data for steaks and roasts, and data on the processing of non-intact steaks and roasts. There were several data gaps identified by NACMCF in addressing its charge (see *Research Needs*).

In January 2002, based on the available data, NACMCF concluded that “non-intact, blade tenderized beef steaks do not present a greater risk to consumers *if* the meat is oven broiled and cooked to an internal temperature of 140 °F or above” (question #1). NACMCF also concluded that “blade tenderized beef steaks would present a greater risk when compared to intact beef steaks if they are cooked to an internal temperature below 140 °F.” (question #1).<sup>3</sup> A primary resource for these conclusions was the Kansas State University study (Spring 1999). Since the KSU study considered only beef steaks and not beef roasts, NACMCF concluded that there was insufficient data to determine if non-intact beef roasts presented a greater risk than intact beef roasts (question #2). In addition, NACMCF concluded that there was insufficient consumer behavior data to determine if traditional cooking methods are

---

<sup>3</sup> These NACMCF statements are based primarily on data published by Kansas State University (Spring 1999). Following inoculation of the surface of intact beef steaks (1/2", \_" or 1 \_" in thickness) with a five-strain cocktail of *E. coli* O157:H7 to approximately 10<sup>7</sup> cfu/cm<sup>2</sup>, single-pass blade tenderization resulted in internalization of approximately 3 x 10<sup>3</sup> cfu/gm or approximately 3-4% of the initial inoculum. It was assumed that the surface of intact beef (subprimals) steaks would typically harbor less than 10<sup>3</sup> coliforms /cm<sup>2</sup> when produced under good manufacturing practices. A worst case scenario is that all of the coliforms may be *E. coli* O157:H7 and that their total numbers may exceed 10<sup>3</sup>/cm<sup>2</sup>.

adequate to destroy *E. coli* O157:H7 translocated to the interior of blade tenderized beef steaks and roasts (question #3). There was also insufficient data for the subcommittee to respond to the issue of labeling non-intact beef products (question #4).

#### 4. RISK ASSESSMENT

##### 2.1. Problem Statement

The majority of steaks and roasts destined for hotel, restaurant, and institutional use in the United States may be subjected to “mechanical tenderization.” This is a process in which large pieces of meat are penetrated, usually in several directions, by sets of needles, or double-edged blades, and then cut into steaks and roasts. Sometimes the needles used are hollow, allowing meat to be injected with solution containing flavorings and/or digestive agents such as papain. The purpose of the process is to make lower grade cuts of beef more tender.

During tenderization, transfer of *E. coli* O157:H7 may occur in two ways: (1) from the surface to the interior of contaminated meat; and (2) from contaminated meat to previously non-contaminated pieces of meat (e.g., cross-contamination via blade tenderization needles and/or recycling of injection fluid). Subsequently, *E. coli* O157:H7 in these non-intact servings may survive cooking and cause illness among consumers.

Taking these issues into consideration and using currently available data, the comparative risk of illness from non-intact (tenderized) beef relative to intact (non-tenderized) beef was quantitatively assessed.

##### 2.2. Methodology

This risk assessment begins with an estimation of the occurrence and extent of *E. coli* O157:H7 contamination in raw intact beef steaks prior to tenderization, models the transfer of *E. coli* O157:H7 during tenderization, the growth and decline in the number of *E. coli* O157:H7 on beef steaks due to storage and handling conditions prior to cooking, the survival of *E. coli* O157:H7 contamination on intact and non-intact beef steaks during cooking, and the subsequent probability of illness (Figure 1).<sup>4</sup> Each of these steps (1-5) along with the data inputs and underlying assumptions are discussed in more detail below.

---

<sup>4</sup> It was assumed that the risk estimates apply to roasts as well as steaks. This assumption was made because data was available only for steaks (e.g., Sporing 1999). In general, roasts are thicker than steaks. Kansas State University found that the longer cooking time required to achieve the same internal temperature in thicker cuts of meat resulted in a greater reduction in the number of *E. coli* O157:H7 (Sporing 1999). As a result, it may be expected that roasts are cooked longer than steaks and there would be a greater reduction in the number of *E. coli* O157:H7. Further research is needed to evaluate the effectiveness of cooking in reducing *E. coli* O157:H7 in roasts compared to steaks.

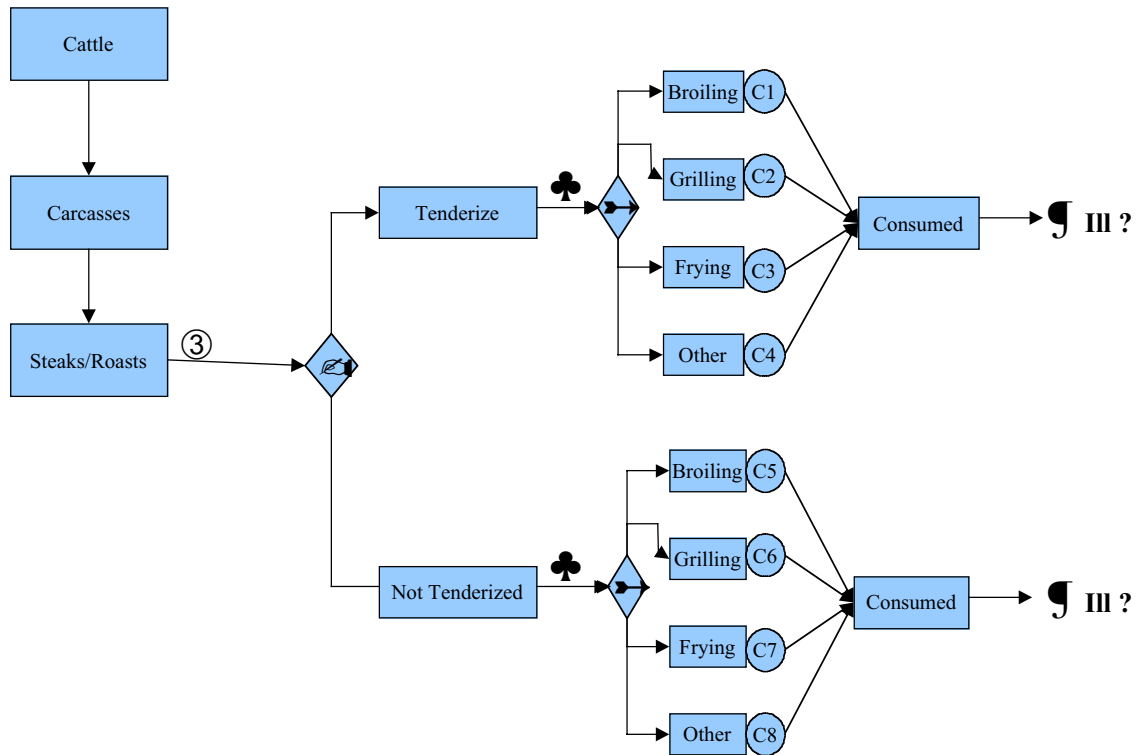


Figure 1. Conceptual process for the production, preparation and consumption of intact (non-tenderized) and non-intact beef (tenderized).

**Step 1. Estimation of the Level of *E. coli* O157:H7 Contamination in Raw Steaks.**

Currently, there is no sampling data available on the prevalence and levels of *E. coli* O157:H7 on, or in, steaks. As a result, the occurrence and extent of *E. coli* O157:H7 contamination on servings of steak had to be estimated based on: (1) the proportion of the carcass that becomes intact or non-intact cuts of beef versus ground beef; and (2) the predicted prevalence and levels of *E. coli* O157:H7 in ground beef servings (Table 1).<sup>5</sup>

Table 1 indicates that of the approximately 0.3% contaminated ground beef servings produced annually, most contain about one *E. coli* O157:H7 organism.

<sup>5</sup> The risk assessment for ground beef (FSIS August 2001) estimated the levels of *E. coli* O157:H7 in ground beef based on data from the FSIS (1994) national baseline survey of slaughter plants. In the 1994 FSIS survey, a 60-cm<sup>2</sup> surface area was sampled from each of 2,081 chilled carcasses originating from feedlots. Four (0.2%) carcasses were *E. coli* O157:H7-positive, and enumerated densities were reported (50% were <0.030 cfu/cm<sup>2</sup> and 50% were between 0.301 and 3.000 cfu/cm<sup>2</sup>). Based on a study using more sensitive detection methods, the actual prevalence of carcasses contaminated with at least 0.03 cfu/cm<sup>2</sup> would be about 5% (Elder 2000). Modeling was used to estimate the fraction of contaminated ground beef servings with various levels of *E. coli* O157:H7 (FSIS August 2001).

Table 1. *E. coli* O157:H7 levels predicted in ground beef servings (FSIS August 2001).

<i>E. coli</i> O157:H7 per serving	Fraction of servings	
	June-September	October-May
0	99.5%	99.8%
1	0.46%	0.19%
3	0.038%	0.011%
10	0.0035%	0.00040%
31	0.0000027%	0.000000002%
100	0%	0%

See: *The Public Health Impact of Escherichia coli O157:H7 in Ground Beef* (FSIS August 2001).

The ground beef risk assessment (FSIS, August 2001) also estimated the proportion of beef processed into prime cuts versus ground beef as follows:

- 75% of a steer/heifer carcasses' original surface area becomes beef trim used to make ground beef,
- 25% of the original surface area's *E. coli* O157:H7 remain to contaminate primal cuts of beef (e.g., steaks and roasts),
- the remaining surface *E. coli* O157:H7 on primal cuts are distributed across about 82% of the weight of the original carcass (i.e., 500 lbs. of beef per carcass and about 18% is trim).

Adjusting the prevalence of *E. coli* O157:H7 in ground beef based on the proportion of carcass that become primary cuts of meat (e.g., steaks and roasts) rather than trim, an estimated 0.02% of steaks produced annually contain *E. coli* O157:H7. Assuming that the *E. coli* O157:H7 organisms are evenly distributed on the surface of carcasses, servings of steaks are estimated to have the same distribution of *E. coli* O157:H7 organisms as in Table 1.<sup>6</sup> To simplify the modeling, it was assumed that steak/roast servings contain either:

- no *E. coli* O157:H7 organisms. (99.98% of the time); or
- one *E. coli* O157:H7 organism (0.02% of the time).<sup>7</sup>

**Step 2. Transfer of *E. coli* O157:H7 During Tenderization.** Mechanical tenderization is performed using a series of stainless steel, double-edged blades or needles. The needles or blades penetrate the meat by cutting through muscle tissues and fibers, rather than

<sup>6</sup> Such an assumption is necessary to derive the estimates from the ground beef risk assessment since both mapped carcasses contamination data or the availability of *E. coli* O157:H7 contamination data for steaks and roasts are lacking. A serving of ground beef is a mixture of trim from many carcasses, while a single serving of steak or roast is from a single carcass. As a result, *E. coli* O157:H7 in ground beef may not be a reasonable surrogate to estimate *E. coli* O157:H7 contamination in steaks. The National Cattleman's Beef Association has conducted additional research on *E. coli* O157:H7 contamination in steaks and plans to make this data available to the FSIS Risk Assessment Division (Bo Regan, personal communication, February 2002).

<sup>7</sup> This assumption did not have much effect on the risk estimates for steak/roast servings since there are > 10 times as many servings with only 1 *E. coli* O157:H7 organism.

tearing the tissue or punching holes. It is estimated that large pieces of meat are pierced three times with about 0.8 needles per cm<sup>2</sup> of meat surface each time the needle head strikes. During this process, *E. coli* O157:H7 can be transferred from the surface to the interior of contaminated meat and/or to meat previously not contaminated (e.g., cross-contamination).

The Kansas State University study indicated that about 3-4% of *E. coli* O157:H7 on the surface of intact steaks is transferred to the interior during single-pass blade tenderization (Sporing 1999). The risk assessment assumed that this data (e.g., 3-4% translocation of surface *E. coli* O157:H7) is reasonably indicative of the results of commercial tenderization. The Kansas State University data also suggests that multiple-pass tenderization may not result in significantly more *E. coli* O157:H7 being translocated from the surface to the interior of meat (see below).

The Kansas State University study also indicated that the amount of *E. coli* O157:H7 translocated into the interior of steaks decreased with increasing depth of penetration. This suggests that most *E. coli* O157:H7 is deposited near the surface of a meat during single-pass blade tenderization and that there are few organisms remaining on a blade to be transferred to greater depths of contaminated meat or to meat that was previously not contaminated. Also, given the very low prevalence and levels of *E. coli* O157:H7 contamination (e.g., 0.02% of steaks with most having only 1 *E. coli* O157:H7 organism), cross-contamination may not be a significant factor in the risk of illness from *E. coli* O157:H7 in non-intact beef when compared to steaks contaminated internally through translocation of *E. coli* O157:H7 during tenderization. As a result, cross-contamination was not modeled in this risk assessment and only single-pass tenderization was considered.

***Step 3. Estimation of growth and decline of E. coli O157:H7 during distribution, storage and handling prior to cooking.*** Large pieces of meat (subprimals), either tenderized or left intact, are then cut into standard pieces (e.g., steaks and roasts) and sold to retail for consumption. Consideration was given to the amount of growth and decline in the level of *E. coli* O157:H7 in intact and non-intact beef products during distribution and storage prior to cooking. Assuming that the growth of *E. coli* O157:H7 is the same in steaks as in ground beef (FSIS August 2001), the risk assessment estimated the following:

- about 50% of steaks have no change in the number of *E. coli* O157:H7 during storage and handling;
- about 49% (range: 20-80%) of steaks have a reduction in the levels of *E. coli* O157:H7 resulting from freezing the product; and
- about 1% of steaks have some growth of *E. coli* O157:H7 during storage and handling.

To simplify the modeling, it was assumed that freezing eliminates *E. coli* O157:H7. Since all contaminated steaks (only 0.02% of all steaks) are modeled as having only 1 *E. coli* O157:H7 organism, freezing would leave, at most, 0.1 *E. coli* O157:H7 organism. This

assumption does not significantly change the risk estimates for non-intact and intact steaks. The fraction of steaks estimated with various levels of *E. coli* O157:H7 contamination (e.g., “bugs per serving” (BPS)) are shown in Figure 1.

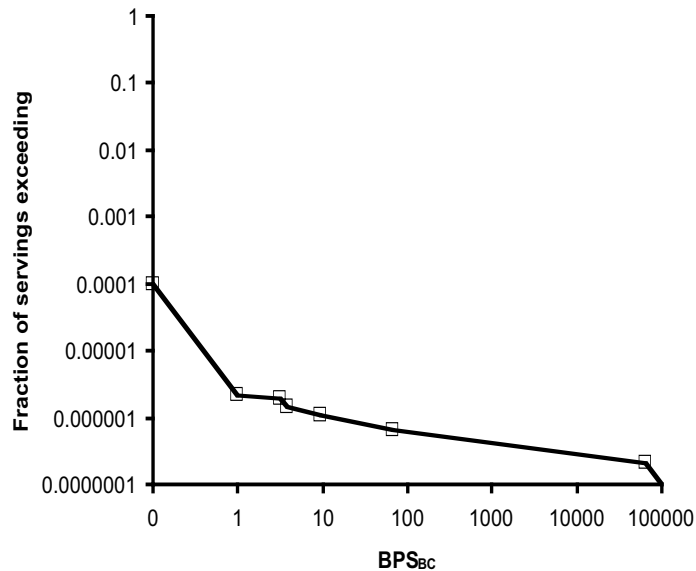


Figure 1. Fraction of steaks contaminated with various levels of *E. coli* O157:H7 organisms prior to cooking (“BPS” = “bugs per serving”).

It is assumed that levels of *E. coli* O157:H7 are the same for non-intact (tenderized) and intact (not tenderized) beef prior to cooking. Figure 1 shows that 99.99% (range: 99.8% to 99.998%) of steaks are not contaminated with *E. coli* O157:H7 after taking into consideration the potential for growth and decline in the number of organisms as a result of storage and handling of these products. Only about 0.01% (range: 0.2% to 0.002%) of steaks contain *E. coli* O157:H7 and most of these contaminated servings contain only 1 *E. coli* O157:H7 organism.

**Step 4. Estimation of the Level of *E. coli* O157:H7 Contamination After Cooking.**

After storage, steaks are prepared by a variety of cooking methods (e.g., broiling, grilling, and frying) prior to consumption. A recent analysis of the USDA Continuing Survey of Food Intakes by Individuals indicates that about 40% of consumers fry steaks, and an equal percent (30%) grill or broil these products (Bogen 2001). This information along with data from the FDA/Audits International Home Cooking Interactive Database<sup>8</sup> was used to estimate the temperatures to which steaks are cooked in the U.S. (FDA 2000) (Figure 3).

<sup>8</sup> The data from the FDA/Audits International Home Cooking Temperature Database do not differentiate between observations for beef, pork or lamb. The lower temperatures in the database were used to represent cooking temperatures for beef since it is likely that pork and lamb are more thoroughly cooked. This more conservative estimate can be adjusted with consumer and retail behavior data as it becomes available.



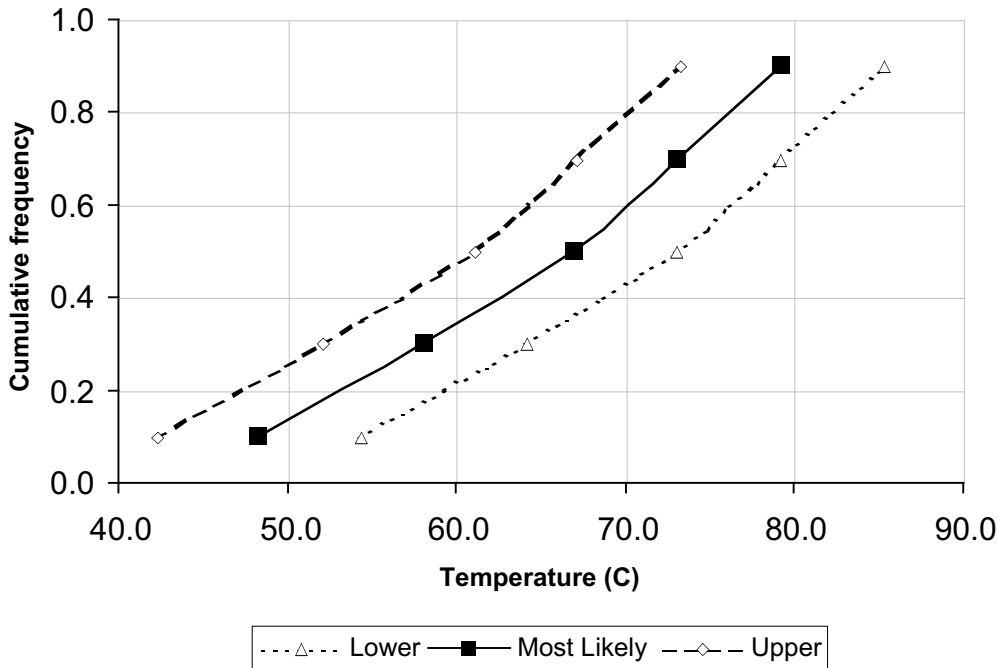


Figure 3: Internal temperature (°C) to which steaks are cooked in the U.S. based on data from the FDA/Audits International Home Cooking Interactive Database.

The Kansas State University study also provided data on the effects of cooking in reducing *E. coli* O157:H7 in non-intact (tenderized) and intact (tenderized) steaks as a function of cooking method (broiling, grilling, and frying), internal temperature, and steak/roast thickness (Spring 1999). The Kansas State University data indicated significant uncontrolled variability in the experiment and a noticeable leveling out, or “plateauing,” effect at the higher temperatures, which is probably due to the limitation in the experiment of inoculating steaks to about  $10^6$  *E. coli* O157:H7. The best fit to this data was drawn taking into consideration the fact that at some temperature all *E. coli* O157:H7 would be destroyed (Figure 4).

The differences in best fit curves for the cooking methods (Figure 4) suggests that the same “internal cooking temperature” in the three cooking methods does not correspond to the same killing conditions in/on the meat. This suggests that there may be another confounding factor not controlled in the Kansas State University study. The movement of curves to the right suggest that *E. coli* O157:H7 is slightly shielded from the effects of cooking in non-intact (tenderized) steaks compared to intact (tenderized) steaks.

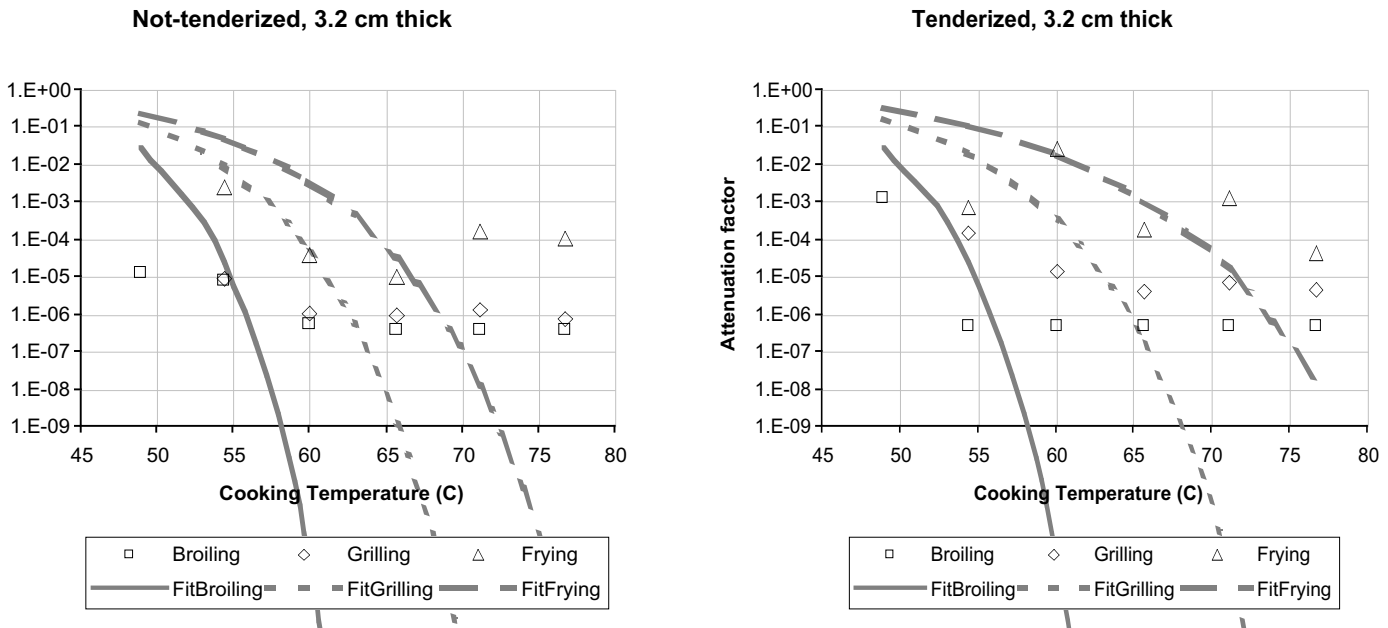


Figure 4: Best fit curves to Sporing (1999) data for broiling, grilling, and frying 3.2 cm thick intact (not tenderized) and non-intact (tenderized steaks). Not shown: data for 1.3 and 1.9 cm thick steaks.

Combining this information, the risk assessment estimates that 0.000026% (i.e., 2.6 of every 10 million servings) of intact steaks contain one or more *E. coli* O157:H7. For non-intact (tenderized) steaks, 0.000037% (i.e., 3.7 of every 10 million servings) contain one or more *E. coli* O157:H7. See Figure 6 for a full range of exposure doses of *E. coli* O157:H7 in intact and non-intact beef.

**Step 5. Dose-Response.** The *E. coli* O157:H7 dose-response relationship shown in Figure 5 was adapted from the ground beef risk assessment (FSIS August 2001) using data from five Japanese foodborne outbreaks (Nauta 2001, Shingawa 1997, Uchimura 1997<sup>9</sup>). The dashed curve is intended to apply to the general population. A dose-response curve for susceptible individuals (e.g., children < 5 years old) would be shifted to the left of this curve (i.e., closer to the Japan 2 young children data point).

This dose-response relationship suggests, for example, that if 100 individuals from the general population each consumed servings containing, say, 10,000 *E. coli* O157:H7 (i.e., 4 logs), about 60 would become ill.

<sup>9</sup> Translated by Dr. Fumiko Kasuga, National Institute of Infectious Diseases, Japan.

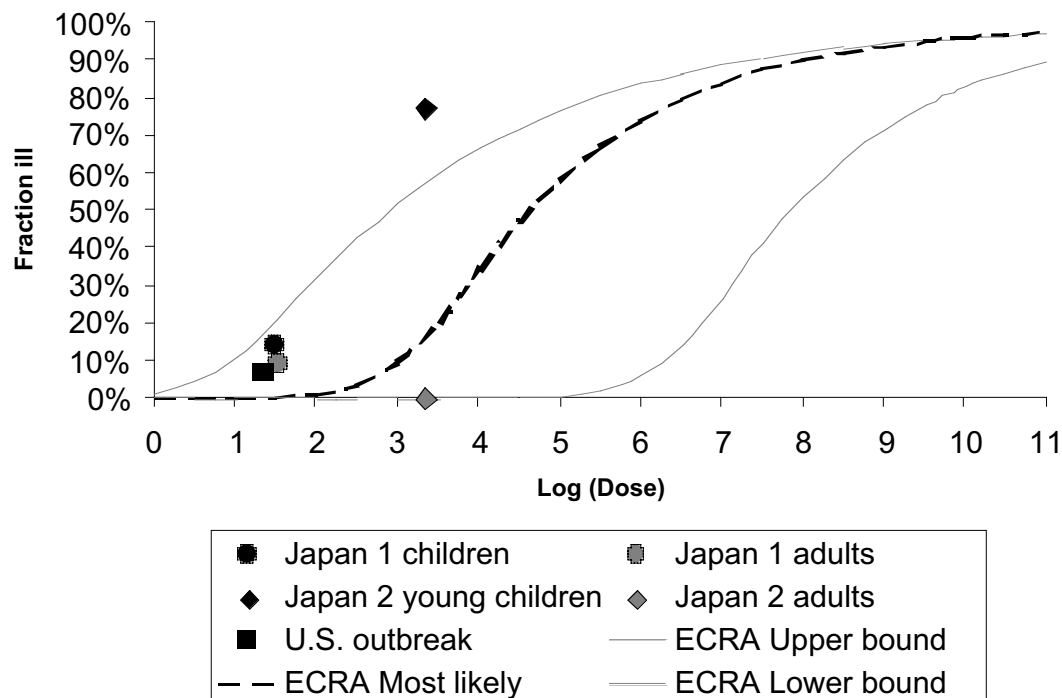


Figure 5. Expected *E. coli* O157:H7 dose-response curve for the general population.

## 2.2. Risk Assessment Results

The probability of *E. coli* O157:H7 surviving typical cooking practices in either tenderized or non-tenderized steaks, is minuscule. As can be seen in Figure 6, 0.000026 percent (i.e., 2.6 of every 10 million servings) of steaks that are intact (not tenderized) contain one or more *E. coli* O157:H7. For non-intact (tenderized) steaks, 0.000037 percent (i.e., 3.7 of every 10 million servings) contain one or more *E. coli* O157:H7. There is almost no difference in exposure to *E. coli* O157:H7 in cooked intact (not tenderized) versus non-intact (tenderized) steaks (see almost overlapping lines in Figure 6).

Figure 6 suggests that illness seldom occurs at doses less than 10 *E. coli* O157:H7 per serving of intact or non-intact beef. At a dose of 100 *E. coli* O157:H7, approximately 16 percent of those exposed will become ill. The fraction of intact (not tenderized) steaks with exposure doses of 100 or more *E. coli* O157:H7 is about 1.4 in 10 million, while the fraction of non-intact (tenderized) servings with exposure doses  $\geq 100$  *E. coli* O157:H7 is about 1.5 in 10 million.

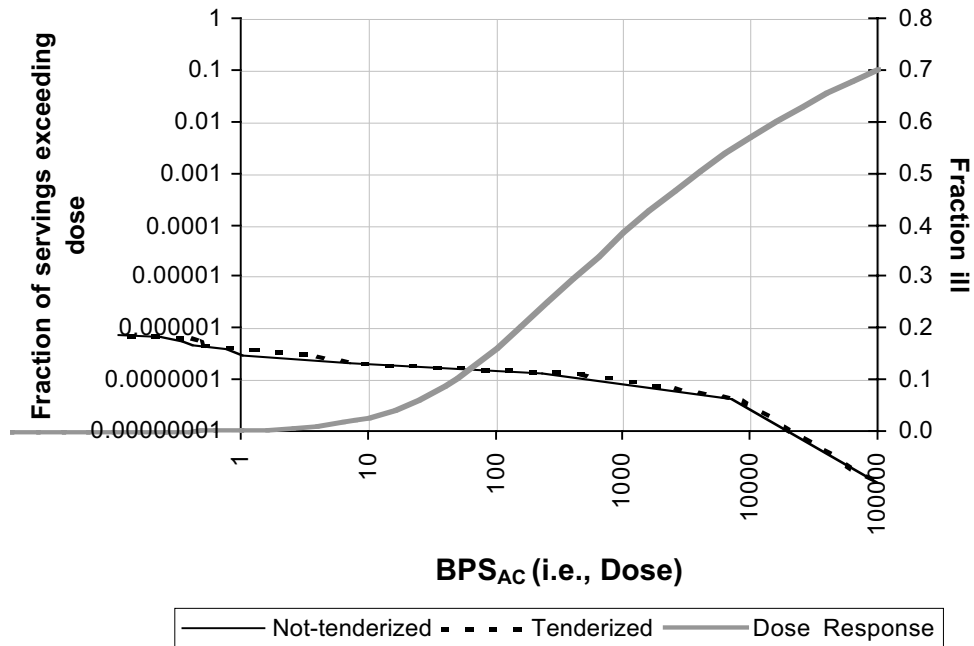


Figure 6. Model output showing predicted bacteria per serving after cooking (exposure dose) and corresponding frequency of illness (response).

Moreover, there is almost no difference in the risk of illness from intact (not tenderized) versus non-intact (tenderized) steaks<sup>10</sup>:

- 1 illness per 14.2 million servings of intact steaks;
- 1 illness per 15.9 million serving of non-intact (tenderized) steaks.

This implies that there would be about seven additional illnesses due to tenderization for every billion steak servings.

### 3. Comparison of Risk Assessment Results to NACMCF Findings

The risk assessment and NACMCF found had somewhat similar findings:

- NACMCF found that non-intact (tenderized) beef does not pose a greater risk of illness than intact beef if it is oven broiled and cooked to an internal temperature of 140°F (45.8°C) or more.
- The risk assessment found almost no difference in the risk of illness from intact versus non-intact (tenderized) steaks regardless of cooking temperature [ 1 illness out of 15.9 for intact steaks compared to 1 illness out of 14.2 millions non-intact steaks].

<sup>10</sup> The risk assessment indicates 80% confidence that the predicted probability of illness from *E. coli* O157:H7 for both intact and non-intact (tenderized) steaks is between  $4.5 \times 10^{-8}$  and  $1.0 \times 10^{-7}$ .

#### 4. Research Needs

The following research needs have been identified in order to obtain more information about the microbiological profile, cooking practices, industry practices for blade tenderizing, and the proportion of blade tenderized beef marketed in the U.S.. Data is also needed regarding the exposure dose of *E. coli* O157:H7 likely to cause illness in susceptible populations.

1. A lack of quantitative (variable) baseline data for *E. coli* O157:H7, or appropriate indicator organisms such as *E. coli* biotype 1, coliforms, and/or *Salmonella*, on primal and subprimal cuts of beef immediately prior to blade tenderization was identified. Ideally, mapped carcass prevalence and level of *E. coli* O157:H7 data should be collected.
2. Data on the type of tenderization, processing conditions, and establishment production volume should be gathered along with baseline data as risk factors useful in as a profile to target Agency inspection resources for HACCP verification activities.
3. Survival of *E. coli* O157:H7 in core beef samples following cooking to specified temperatures, including data on the survival of *E. coli* O157:H7 in beef roasts compared to beef steaks.
4. Industry and consumer practices for cooking various cooking methods (e.g., grill vs. broil).
5. Industry practices for blade tenderization; such as the type of machine, number of passes through the tenderizer, sanitation of equipment, through put, temperature of the processing room, and the temperature of the primal cuts.
6. Proportion and quantity of blade-tenderized beef distributed to retail and food service establishments.
7. Better understanding of the heat and mass transfer characteristics of blade-tenderized meats cooked by various means.
8. Quantify the heat resistance (e.g., D and z values) of the individual strains of *E. coli* O157:H7 used in the Sporing (1999) study. Individual strains should be identified and characterized.
9. Dose-response relationship for susceptible populations (e.g., children < 5 years old). Exposure dose data could be collected during outbreak investigations.

## 10. References

Bogen KT and Keating GA (2001). U.S. dietary exposure to heterocyclic amines. *J Exposure Analysis and Environmental Epidemiology* 11(3):155-168.

Elder RO, Keen, JE, Siragusa, GR, Barkocy-Gallagher GA, Koomaraie, and Laegreid WW (2000). Correlation of enterohemorrhagic *E. coli* O157 prevalence in feces, hides, and carcasses of beef cattle during processing. *Proc Natl Acad Sci* 97(7):2999-3003.

Food and Drug Administration (2000). Audits International/FDA home Cooking Temperature Database. See: <http://www.foodriskclearinghouse.umd.edu/ColdFusion/ Cooking/>

Food Safety and Inspection Service (1994). Nationwide Beef Microbiological Baseline Data Collection Program: Steers and Heifers – October 1992-September 1993

Food Safety and Inspection Service (2001a). Risk Assessment Plan for Non-Intact Beef. Janell Kaue, Hazard Analysis and Regulatory Affairs Staff, Office of Public Health and Science. December 18, 2001.

Food Safety and Inspection Service (2002). Technical Report: Comparative Risk Assessment for Intact (Non-Tenderized) and Non-Intact (Tenderized) Beef. Stan Kaplan, Eric Ebel, and Wayne Schlosser, Modeling and Exposure Assessment Staff, Office of Public Health and Science. March 2002.

Food Safety and Inspection Service (August 2001). Draft Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef. Risk Assessment Division, Office of Public Health and Science. [Currently under review by the National Academy of Science]. See: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-023NReport.pdf> a n d <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-023N/InterpretiveSummary.pdf>.

Health Canada (March 2002). Reported cases of illness associated with tenderized beef. One page of summary information from the Quebec Center of Food Inspection and Animal Health provided by Dr. Anna Lammerding.

Kansas State University. (August 3, 2001). Presentation: "Evaluation of Pathogen Risks Associated with Blade Tenderized Beef Cooked to Varying Degrees of Doneness." National Advisory Committee for Microbiological Criteria for Foods (NACMCF) meeting, Washington, DC.

Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C, Griffin PM, and Tauxe RB (1999). Food-related illness and death in the United States. *Emerg Infect Dis* 5(5):607-625.

Michigan Department of Community Health/Communicable Disease and Immunization Division (August 2000). Report: Foodborne Illness Investigation: *E. coli* O157.

National Advisory Committee for Microbiological Criteria for Foods (January 25, 2002). Final Report: *E. coli* O157:H7 in Blade Tenderized Beef. See: [http://www.fsis.usda.gov/OPHS/NACMCF/2002/rep\\_blade1.htm](http://www.fsis.usda.gov/OPHS/NACMCF/2002/rep_blade1.htm).

Nauta, M.J., E.G. Evers, K. Takumi and A.H. Havelaar. 2001. Risk assessment of Shiga-toxin producing *E. coli* O157:H7 in steak tartare in the Netherlands. RIVM report 257851003.

Shinagawa, K. et al. Correspondence and problem for Enterohemorrhagic *E. coli* O157 outbreak in Morioka city, Iwate. Bulletin of National Institute of Public Health, Vol. 46, No. 2, 104-112, 1997. (Japanese publication translated and interpreted by Dr. Fumiko Kasuga).

Spring, Sarah B (1999). *E. coli* O157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steaks. Kansas State University Master of Science thesis. Professor: Randall K. Phebus.

Uchimura, M. et al. An outbreak of Enterhemorrhagic *E. coli* O157 in a daycare – Chiba Prefecture. Infectious Agents Surveillance Report, Vol. 18, No. 12, 309-310, 1997. (Japanese publication translated and interpreted by Dr. Fumiko Kasuga).

Wisconsin Department of Health and Family Services/Wisconsin Division of Public Health (October 2000). Report: Investigation of an Outbreak of *E. coli* O157:H7 Infection at the Layton Avenue Sizzler Restaurant, Milwaukee, WI; July-August 2000.