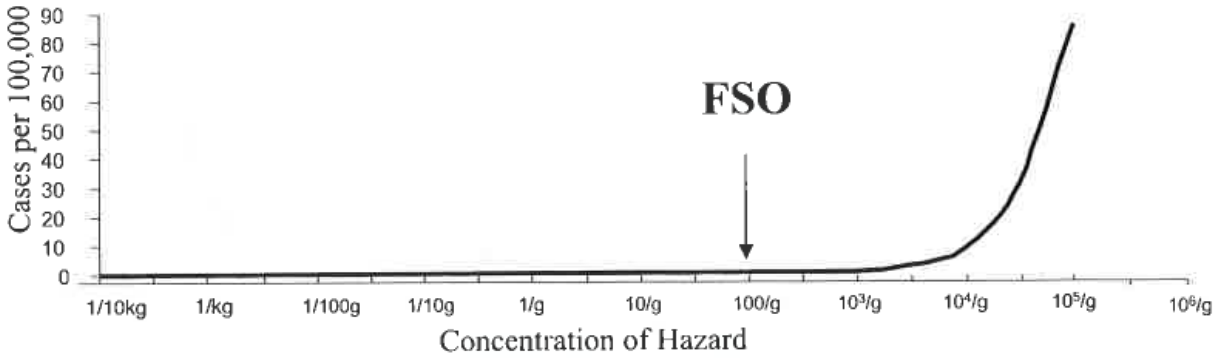


1) Cooking

$\leftarrow H_0$

$\Sigma R = 6$

2) Assume that if contamination occurs, it could be as as high as 10 g^{-1} ($\Sigma I = 4$)

$\rightarrow$

$\Sigma I = 4$

3) To eliminate the contamination that may occur between cooking and packaging and meet the performance criterion of ≤ 1 kg^{-1}, a 4-$\log_{10}$ reduction step is needed

$\leftarrow$

$\Sigma R = 4$

Figure 16–3c Control measure: reducing levels using in-package pasteurization.

16.3.4.6 Reducing Levels Prior to Consumption

If the product is recontaminated with *L. monocytogenes* to a level of 10 g^{-1} (I=4) and growth does occur during subsequent distribution and storage, then the handling and preparation procedures become very important for susceptible consumers. If it is assumed that there could be a 5 $\log_{10}$ increase due to growth (I=5) between when the frankfurters are cooked in the factory and when they are reheated for serving, then the combined increase after cooking would be $\Sigma I = 4 + 5$ for a total increase of 9 $\log_{10}$. At the time of preparation, the frankfurters would have a level of 10^6 g^{-1}. This could be represented as follows (see also Figure 16–3e).

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$3 - 6 + 9 \leq FSO$$

$$H_0 - \Sigma R + \Sigma I \leq 6$$

Therefore, to meet the required FSO of ≤ 100 g^{-1}, an additional reduction step during preparation for serving would be required prior to consumption, as follows.

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$3 - \Sigma R + 9 \leq 2$$

$$\Sigma R \leq 10$$

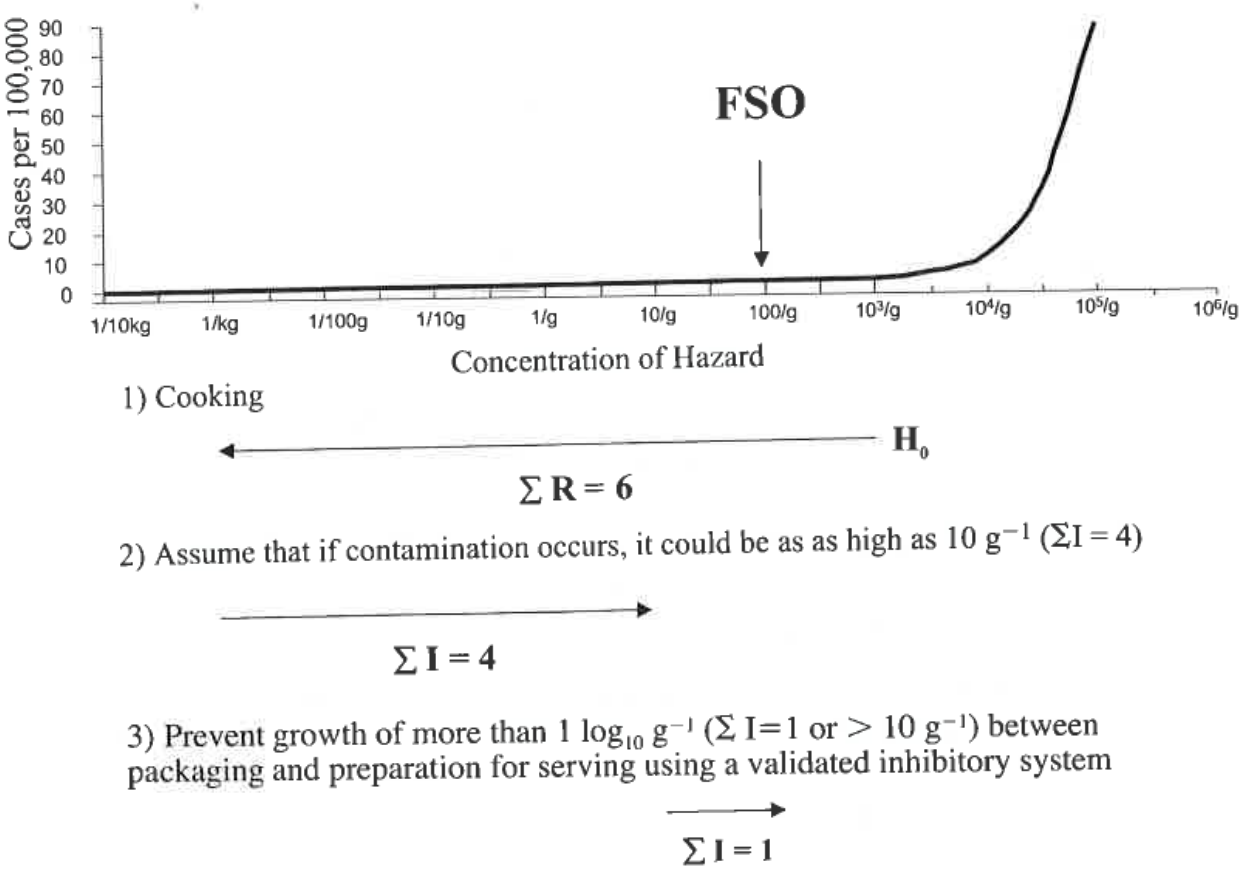


Figure 16–3d Control measure: use of inhibitor(s) to prevent growth after packaging.

After taking account of the 6 $\log_{10}$ reduction (i.e., $\Sigma R = 6$) that occurs when the frankfurters were cooked during manufacture, the reduction during preparation for serving must be at least as follows (Figure 16–3e).

$\Sigma R \leq 4$

The final reheating before serving then must reduce the level of *L. monocytogenes* by 4 $\log_{10}$ to ensure that the frankfurters will meet the FSO of 100 g^{-1} at the time they are consumed.

16.4 PROCESS AND PRODUCT CRITERIA

Each manufacturer must determine the parameters for cooking that will provide the desired product quality and cost, and, in this example, ensure that the performance criterion (i.e., < 1 kg^{-1}) is met for cooking. The parameters adopted by one manufacturer may differ from those adopted by others. This is due to differences in equipment, desired product quality, type of raw materials (e.g., beef, pork, chicken and/or turkey), type of casing (e.g., natural, artificial), method of applying smoke (e.g., natural, liquid), fat content, and other factors. To meet the performance criterion requires knowledge of the heat sensitivity of *L. monocytogenes*, particularly in frankfurter emulsions.

Historically, the minimum internal requirement set by USDA for cooked sausage was 64.4 °C. For frankfurters, industry typically applied processes to achieve at least 68.3 °C. Since about 1980–1985, many processors have increased the temperature to 71 °C, or

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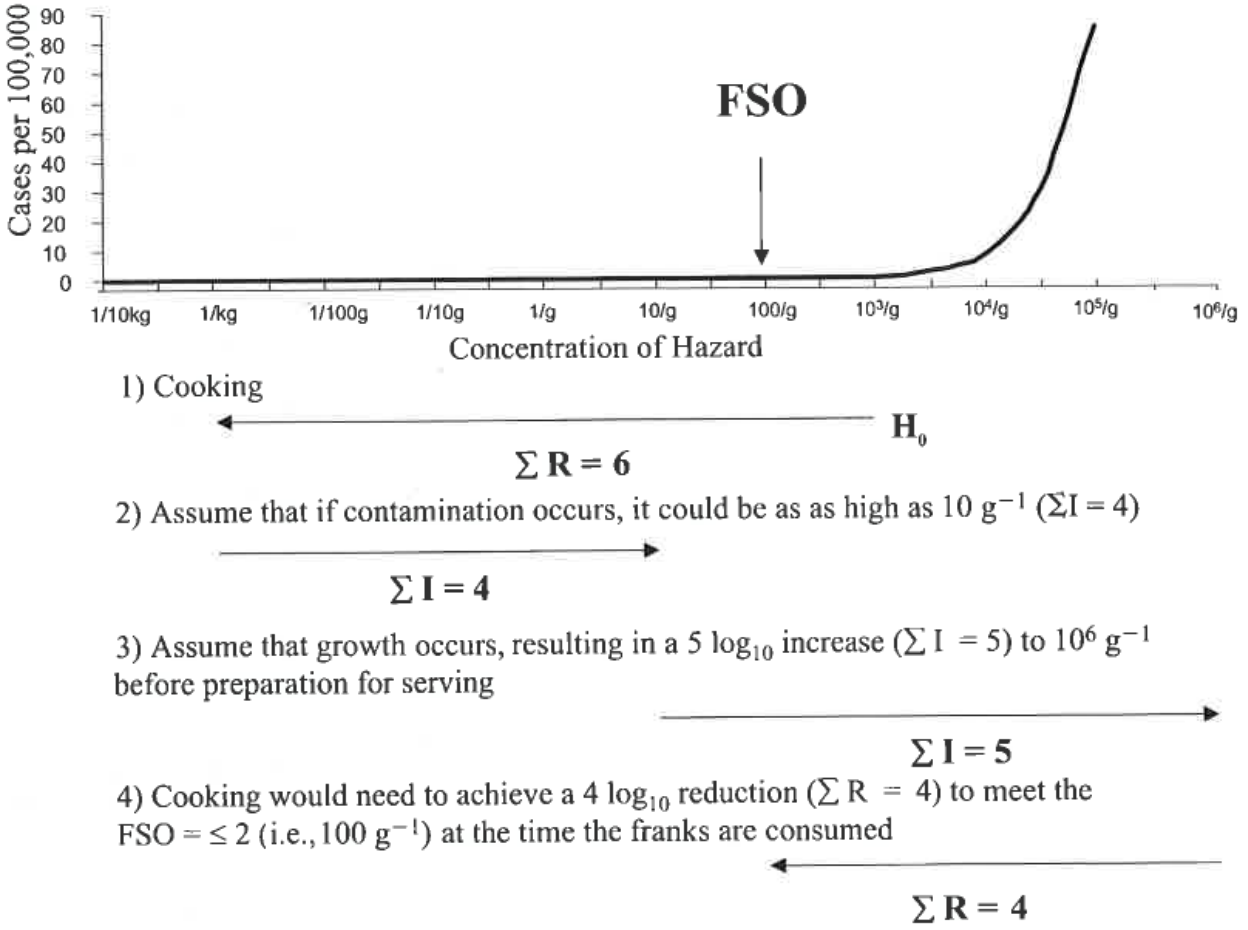


Figure 16–3e Control measure: reducing levels prior to consumption.

higher, to achieve greater consistency in product quality and refrigerated shelf-life. Even with the minimum requirement of 64.4 °C, however, there was no evidence that cooked sausages were implicated as a source of foodborne illness due to survival of enteric pathogens, probably due to the low concentration of enteric pathogens present initially and their sensitivity to heat. In the case of *L. monocytogenes*, the data in Table 16–4 indicate that survival also is unlikely to occur. Even with extensive testing for the pathogen since 1988, there has been no documented incident in which *L. monocytogenes* surviving the heat process was the underlying reason for a contaminated cooked sausage.

The thermal process can be validated by various means. One could be to conduct thermal destruction tests in the laboratory using frankfurter emulsion inoculated with a mixture of *L. monocytogenes* isolates from meat operations. Another may be to perform in-house challenge experiments with nonpathogenic surrogate organisms, such as *L. innocua*. Various items, such as provided in Chapter 3, should be considered when conducting such studies to validate a thermal process. A third approach to validation is to review the published literature for data on thermal resistance. For example, numerous studies have been published that report thermal destruction values for *L. monocytogenes* in various meat and poultry products (ICMSF, 1996; Farber & Peterkin, 1999; Zaika *et al.*, 1990; Fain *et al.*, 1991).

The data summarized in Table 16–4 provide lethality values for *L. monocytogenes* in meat, poultry, and seafood cooked to temperatures within the range of 60–65 °C. A number of factors influence the rate of death, but from the data, it can be concluded that even

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Table 16–4 Reported Thermal Destruction Values for *L. monocytogenes* in Meat, Poultry, and Seafood Products

Product	*Temp (°C)*	*D value* (min.)*	*Reference*
Ground meat with cure mix	64	2.28	Farber (1989)
Ground meat	64	<1.01	
Beef	65	0.93	Mackey *et al.* (1990)
Chicken leg	65	0.53	
Chicken breast	65	0.52	
Buffer	65	0.29	Boyle *et al.* (1990)
Meat slurry	65	0.75	
Lean beef	62.8	0.6	Fain *et al.* (1991)
Fatty beef	62.8	1.2	
Beef steak	63.9	2.2	Gaze *et al.* (1989)
Chicken breast	63.9	1.6–1.8	
Ham—control culture	60	1.8	Carlier *et al.* (1996)
Ham—heat-shocked culture	60	3.5	
Ham—"resistant" culture	60	1.0	
Mussels	62.2	1.85	Bremer & Osborne (1995)
Crabmeat	60	1.3–2.6	Harrison & Huang (1990)
Lobster meat	62.8	1.1	Budu-Amoako *et al.* (1992)
Salmon	65	0.9–1.2	Embarek & Huss (1993)
Cod	65	0.27–0.28	
Cured sausage blend of 66% pork and 33% beef	63.9	3.3	Farber & Brown (1990)
Cured sausage blend of 66% pork and 33% beef	30 min. at 47.8 °C, then heat to 63.9 °C	4.2	
Cured sausage blend of 66% pork and 33% beef	60 min. at 47.8 °C, then heat to 63.9 °C	4.7	
Cured sausage blend of 66% pork and 33% beef	120 min. at 47.8 °C, then heat to 63.9 °C	8.0	

*D value = time in minutes at a specified temperature for a one $\log_{10}$ (i.e., ten-fold) reduction in the number of *L. monocytogenes*.

these lower temperatures are effective for killing *L. monocytogenes* in a wide variety of foods. Such data can be used to arrive at alternative thermal processes for sausage products, such as frankfurters, and to consider the disposition of products in the event of a deviation. The adequacy of a thermal process based on an internal temperature of 70 °C can be determined from the data in Table 16–5.

An example of a default process criterion to achieve a 6 $\log_{10}$ reduction for in-pack pasteurization can be found in the draft Code of Practice developed by a Belgium-Dutch Chilled Meals Working Group, which recommends an internal heat treatment of 70 °C for 2 minutes for elimination of *L. monocytogenes* in chilled, long-life pasteurized foods (Lund & Notermans, 1993). The advantage in using a performance criterion rather than a default process criterion is that it allows flexibility in how the performance criterion is achieved. This would facilitate the development of new technology that may offer novel ways to achieve the same end result.

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Table 16–5 Reported D values for *L. monocytogenes* at 70 °C

Product	*D value (min)**	*Reference*
Beef	0.14	Mackey *et al.* (1990)
Chicken leg	0.11	
Chicken breast	0.13	
Meats (predicted value)	0.13	
Meat slurry	0.23	Boyle *et al.* (1990)
Beef slurry (pH 5.9)	0.23	
Phosphate buffer (pH 7.2)	0.15	
Chicken	0.16, 0.20	Gaze *et al.* (1989)
Beef steak	0.20, 0.14	
Turkey meat emulsion	0.35	Fain *et al.* (1991)
Salmon, cod	0.13–0.17	Embarek *et al.* (1993)
Sucrose solution, a_w 0.98	0.15 @ 68.3C	Sumner *et al.* (1991)
Sucrose solution, a_w 0.96	0.30 @ 68.3C	
Raw milk	0.05 @ 68.9C	Bradshaw *et al.* (1985)
Raw milk	0.015@ 71. 7C	

*D value = time in minutes at a specified temperature for a one $\log_{10}$ (i.e., ten-fold) reduction in the number of *L. monocytogenes.*

Product criteria that are intended to prevent growth after packaging could be validated by performing challenge studies using surface-inoculated frankfurters to assess the likely increase (ΣI) of *L. monocytogenes* to $\geq$ 100 g^{-1} before the recommended use-by date. Challenge studies could involve, for example, using commercial product inoculated and packaged in a laboratory with a mixture of five isolates of *L. monocytogenes* and then stored at temperatures to which the product would be exposed during storage and distribution. Many factors should be considered when conducting such studies (see Chapter 3). Predictive modeling also can provide an estimate of the pathogen's behavior and possible growth or inactivation (McKellar *et al.*, 1994; Armitage, 1997; McClure *et al.*, 1997; McDonald & Sun, 1999; Buchanan & Whiting, 1996).

Examples of additives that have been found effective for inhibiting *L. monocytogenes* include sodium lactate, sodium acetate, and sodium diacetate (Schmidt, 1993; Schmidt & Leistner, 1993; Qvist *et al.*, 1994; Wederquist *et al.*, 1994, 1995; Blom *et al.*, 1997; Tompkin, 1999; Juncher *et al.*, 2000; Hoogenkamp & Wales, 2000).

A uniform procedure has not been developed to validate code-dating practices to ensure the safety of perishable foods with extended shelf-life (e.g., frankfurters and other cooked meat or poultry products). As discussed in Chapter 3, a number of factors must be considered when validating the effectiveness of one or more steps along the food chain. The following factors should be considered when performing a validation study for code-dating frankfurters:

- physiological state of the inoculum (e.g., 24 h broth culture)
- method of inoculation (surface)
- inoculum level (per package or per g)
- source and number of strains

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- virulence of the strains (outbreak strains should be avoided in most laboratories)
- temperature(s) of storage
- natural competitive flora (commercial v. pilot plant product)
- product formulation (fermentable carbohydrate and rate of acid production).

16.5 GHP AND HACCP

Certain aspects of GHP must be controlled to minimize recontamination of cooked products, as has been discussed in this chapter and Chapter 11. In this example, a performance criterion of ≤ 1 kg^{-1} was established for the cooked product and for in-package pasteurization to ensure that the FSO of ≤ 100 g^{-1} is met. This led to the establishment of process criteria that could be adopted as critical limits in the HACCP plan. The critical limits typically consist of a holding time and internal temperature, their selection being influenced by the cooking system (e.g., continuous or batch oven). If, for example, 71 °C is adopted, the critical limit for cooking frankfurters during their manufacture could be stated as "an internal temperature of 71 °C", a hold time not being necessary.

With a properly designed and implemented HACCP plan, there would be no benefit to testing the cooked product for further validation of the process or to verify that each lot has been cooked correctly. If an event occurs requiring such testing, then a sampling plan of $n = 5$, $c = 0$, $m = 0/25$ could be used. This would provide 95% confidence of detecting a positive lot if the mean count was 0.03 cfu g^{-1} or greater.

16.6 ACCEPTANCE CRITERIA FOR FINAL PRODUCT

16.6.1 Organoleptic

No organoleptic criteria are applicable to assess the likely presence of *L. monocytogenes* in frankfurters.

16.6.2 Chemical and Physical

No chemical or physical criteria are applicable to assess the likely presence of *L. monocytogenes* in frankfurters.

16.6.3 Microbiological

When it is known that a product has been pasteurized in the pack, sampling final product would provide no added value and is not recommended. Likewise, for those plants that are using a validated kill step for cooking and where an effective environmental sampling program documents that the risk of recontamination is being controlled, there is little value in testing end product. The reason is that a comprehensive management system can maintain frequencies of contamination to less than 0.5%. Under these circumstances, the frequency of defective units is too low for detection with any practical sampling plan (see Chapters 6, 7, and 17).

Where product is crossing international borders and nothing is known about the product or the manufacturing process, end-product testing may be appropriate. The ICMSF has provided guidance on sampling plans for *L. monocytogenes* in a variety of foods and conditions (van Schothorst, 1996). For frankfurters that have not been in-pack pasteur-

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ized and, if contaminated, growth could occur (e.g., no added inhibitors), ICMSF sampling case 12 ($n = 20$, $c = 0$) would apply. When case 12 is applied and 25 g analytical units are used in a two-class sampling plan, which would be typical for *L. monocytogenes*, there is 95% probability that a positive lot would be detected when the mean concentration is 1 cfu in 186 g or greater. This assumes a log-normal distribution and standard deviation of 0.8. Thus, the sampling plan performance would be adequate to detect lots that exceed an FSO of $\geq 100\ g^{-1}$. If the frankfurters are intended specifically for highly susceptible individuals (e.g., hospitals), then case 15 would apply ($n = 60$, $c = 0$). When case 15 is applied and 25 g analytical units are used, there is a 95% probability that a positive lot would be detected when the mean concentration is 1 cfu in 526 g or greater.

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E. coli O157:H7 in Frozen Raw Ground Beef Patties

17.1 Introduction
17.2 Risk Evaluation
17.3 Risk Management
17.4 Control Measures
17.5 Acceptance Criteria
17.6 Statistical Implications of the Proposed Sampling Plan
17.7 References

17.1 INTRODUCTION

This chapter is concerned with *Escherichia coli* O157:H7 in frozen raw ground beef patties. The information follows the principles outlined in earlier chapters. The unique severity of the pathogen and its impact among children under five years of age warrant special consideration. In this example, the merits of microbiological testing will be explored as a potential control measure to enhance the safety of ground beef. A significant portion of this material was published as a discussion paper (Tompkin & Bodnaruk, 1999). This example draws primarily on data from the US. The information may be applicable in other countries with similar prevalence rates in ground beef and where undercooking is a risk factor.

Ground beef is an important raw agricultural commodity. In 1992 in the US, the types of cattle from which ground beef was derived were steers, 39.1%; heifers, 19.2%; cows, 34%; and bulls, 7.7%. Imported boneless manufacturing beef composed 15% of the total US ground beef supply. Imports into the US account for almost half of the world trade in fresh, chilled, and frozen beef. Ninety percent of the beef imported into the US is from Australia, New Zealand, and Canada. Other sources include Costa Rica, Honduras, and the Dominican Republic. The annual average quantity of beef imported into the US has been over 600,000 tons (USDA, 1994). Annual per capita consumption was estimated to be about 11.8–12.7 kg from 1982–1998 (AMI, 2000). Ground beef is consumed in the form of hamburger and as a major ingredient in a variety of foods.

E. coli O157:H7 is among the more newly recognized foodborne pathogens, being first identified during an outbreak in 1982 in which ground beef was implicated. It has since been a steadily increasing cause of foodborne illness worldwide. It is recognized that there are numerous serotypes of enterohemorrhagic *E. coli* (EHEC), some of which may be more important in certain regions of the world than *E. coli* O157:H7 (WHO, 1997; Acheson, 2000).

Since 1982, ground beef has become recognized as a major vehicle for transmission of *E. coli* O157:H7 in the US. In general, the pathogen is deposited on the surface of beef carcasses during the slaughtering process. After chilling, the carcasses are cut into large portions for sale as bone-in or boneless beef cuts (e.g., round, loin, rib, chuck). During this

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process, the larger portions are trimmed of excess fat and other tissue. The trimmings commonly are used in the manufacture of raw ground beef and a wide variety of ready-to-eat products (e.g., sausages). The same process of trimming meat and fat occurs at other steps along the food chain, with much of it being used for ground beef. Wherever it may occur along the food chain, the process of trimming and subsequent grinding distributes the pathogen throughout the ground meat. The most common scenario leading to illness has involved undercooking, survival of the pathogen, and subsequent infection, particularly among the more susceptible consumers. Cross-contamination in kitchens and food service establishments from ground beef to other ready-to-eat foods also has occurred.

It is extremely difficult to compare data from different countries on incidence and prevalence due to the use of different methods of sampling/reporting. However, data for different countries indicate that *E. coli* O157:H7 is an international concern, with the prevalence in meat ranging from around 0.1%–5% and prevalence in cattle ranging from around 1.5%–28% (Table 17–1).

17.2 RISK EVALUATION

17.2.1 Hazard Identification

E. coli is a species of Gram-negative, facultatively anaerobic, rod-shaped bacteria commonly found in the lower part of the intestine of warm-blooded animals. *E. coli* O157:H7 is a particular serotype of the group referred to as enterohemorrhagic *E. coli* (EHEC). This is a subgroup of the verocytotoxigenic *E. coli* (VTEC) that has been shown to cause human illness. VTECs produce verotoxins, or shiga-like toxins, that are closely related to the toxin produced by *Shigella dysenteriae* (Cassin *et al.*, 1998). Most EHEC isolates are acid-tolerant, capable of surviving in acid foods and during passage through the stomach (Benjamin & Datta, 1995; Arnold & Kaspar, 1995; Leyer *et al.*, 1995; Cheville *et al.*, 1996).

Table 17–1 Incidence of *E. coli* O157:H7 Infection and Prevalence in Meat and Cattle in Various Countries

Country	*Incidence HUS/VTEC*†*	*Prevalence (%) in Meat*	*Prevalence (%) in Cattle*
Argentina	HUS 7.8 per 100,000	0.4 bovine meat	
Australia	HUS 2.79 per 100,000		
Canada	VTEC 3.0 per 100,000		
Denmark	VTEC 0.1 per 100,000	0.13 minced beef	1.5
Germany		0.7 beef	
		5.0 minced beef	
Japan		0.3 carcass	1.4
Netherlands	30 per year	0.08 beef/pork	11.1
England and Wales	VTEC 1.29 per 100,000	1.5 beef	15.6
US	0.74 per 100,000	1.0	5
			28‡

*HUS = hemolytic uremic syndrome
†VTEC = verocytotoxigenic *E. coli*
‡using improved isolation methods

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Cattle appear to be the main reservoir of *E. coli* O157:H7. Contamination of carcasses during slaughter is the primary route that ultimately leads to contamination of ground beef. Other foods (e.g., lettuce, sprouts, fruit juices, vegetables, raw milk) and water also have been implicated as vehicles of transmission. Person-to-person is an important mode of transmission, particularly in day care centers. Direct contact with animals carrying the organism is also a recognized source of infection (WHO, 1997).

17.2.2 Hazard Characterization

E. coli O157:H7 infection can result in moderate to severe disease or death, with most deaths occurring in children under five years of age and in the elderly (AGA, 1994; Tarr, 1994). Studies conducted in FoodNet sites in the US suggest that from 13–27 cases of infection occur in the community for each confirmed case that is reported (Mead *et al.*, 1999). Within the FoodNet sites, the annual laboratory-confirmed case rate per 100,000 population has been from 2.1–2.8 in the four years of 1996–1999 (CDC, 2000).

The time to onset of symptoms following exposure ranges from three to nine days, with an average of four. The duration of illness ranges from two to nine days; however, with complications, the illness may last many months and lead to permanent damage or even death. Symptoms may include hemorrhagic colitis: grossly bloody diarrhea, severe abdominal pain, vomiting, but no fever; hemolytic uremic syndrome (HUS): prodrome of bloody diarrhea, acute nephropathy, seizures, coma, and death; and thrombotic thrombocytopenic purpura: similar to HUS but also fever and central nervous system disorder (ICMSF, 1996).

The potent toxins of *E. coli* O157:H7 can initially cause a particularly severe form of human disease, hemorrhagic colitis. About 10% of these patients can go on to develop HUS, characterized by acute renal failure, hemolytic anemia, and thrombocytopenia, which is particularly serious in young children and elderly people. On average, 2–7% of patients with HUS die, but in some outbreaks among the elderly, the mortality rate has been as high as 50% (WHO, 1997). Long-term renal dysfunction occurs in about 10–30% of survivors of HUS. The estimate for the prevalence of HUS in North America is about 3/100,000 children under five years of age per year (Mahon *et al.*, 1997).

From outbreak data, it appears that fewer than 100 cells can cause disease among consumers (AGA, 1994), particularly those at greater risk (e.g., less than five years of age) (Mahon *et al.*, 1997). In the 1993 northwestern US outbreak involving undercooked hamburgers, it was estimated that as few as a dozen cells may have caused illness among children (Tarr, 1994).

There are estimated to be about 73,480 cases of illness attributed to *E. coli* O157:H7 per year in the US, of which 85% are estimated to be foodborne. The number of hospitalizations and deaths due to foodborne transmission of this pathogen was estimated to be 1,843 and 52 per year, respectively (Mead *et al.*, 1999). These values differ significantly from the earlier estimates of Mahon *et al.* (1997). The more recent estimate revealed more cases, but fewer deaths. The estimated costs of medical treatment and lost productivity range from $216–580 million/year (AGA, 1994).

17.2.3 Exposure Assessment

The source of *E. coli* O157:H7 on beef carcasses is the hide and intestines of the cattle being slaughtered. Prevalence among cattle being held for slaughter is similar to or

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slightly higher than the prevalence on the external surface of hides of recently slaughtered animals (Hancock, 1998).

The percent of cattle with *E. coli* O157:H7 in their feces was initially reported to be typically less than 5% (Hancock, 1998). A later study involving a more sensitive analytical method found 28% of the cattle entering slaughtering plants to be actively shedding *E. coli* O157:H7 or nonmotile *E. coli* O157 in their feces during July and August, the months of highest prevalence. Eleven percent of the hide surfaces also were positive (Elder *et al.*, 2000).

Studies have shown that colonization of cattle is of short duration (1–2 months); long-term carriers have not been found. The typical pattern of shedding in a herd followed over time is one of epidemics of shedding interspersed with longer periods with rare or non-shedding animals. These epidemics occur mainly during warm weather, suggesting that environmental proliferation may play an important role in the epidemiology of *E. coli* O157:H7 (Hancock, 1998). It is important to note that *E. coli* O157:H7 does not cause any adverse effects in cattle. Its presence in a herd or individual animal can be detected only by microbiological testing.

While some cross-contamination may occur from carcass-to-carcass through contact with common equipment and workers' hands, there is no published evidence that *E. coli* O157:H7 has ever become established and multiplied in a slaughtering/chilling/fabrication operation and contaminated subsequent lots of beef.

Technology is currently available that can:

- minimize carcass contamination during the slaughtering process,
- reduce the likelihood of microbial attachment to exposed tissues, and
- decontaminate carcasses, such as with steam, hot water, or organic acid sprays prior to chilling.

Collectively, the above control measures can significantly reduce, but not eliminate, the likely presence of enteric pathogens on raw beef. Systems for decontamination will likely involve multiple control measures during slaughtering, evisceration, and chilling (Dorsa *et al.*, 1996; Dorsa, 1997; Castillo *et al.*, 1998; Nutsch *et al.*, 1998; Sofos & Smith, 1998; Sofos *et al.*, 1999; Bacon *et al.*, 2000).

It is reasonable to assume that when present, *E. coli* O157:H7 is on the surface of carcasses, not in internal tissues. Rapid chilling of adequately spaced carcasses should retard *E. coli* O157:H7 growth on carcass surfaces. Surface dehydration during chilling is an additional factor that can restrict growth.

After chilling, it is not likely that *E. coli* O157:H7 will multiply during subsequent fabrication because the lower temperature limit for multiplication of *E. coli* O157:H7 is 7–8 °C (ICMSF, 1996). Furthermore, estimates for growth under optimum laboratory conditions in broth indicate that:

- at 10 °C, the time to increase 10-fold is estimated to be 73 h, and
- at 15 °C, the time to increase 10-fold is estimated to be 25 h (Buchanan & Whiting, 1996).

Thus, in controlled chilling/fabrication operations, the concentration of *E. coli* O157:H7 should not increase. Conversely, in operations that do not address chilling/fabrication as important factors requiring control, some degree of multiplication may occur.

Epidemiologic data for outbreaks reported each year by the Centers for Disease Control and Prevention (CDC) indicate the risk of *E. coli* O157:H7 from beef continues

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to be associated with consumers who have not changed their handling/cooking habits to control the risk of the pathogen. These consumers do not understand the risks and/or do not have the knowledge to deal with a pathogen such as *E. coli* O157:H7. Some may be aware of the risk and have chosen to ignore recommendations for proper handling and cooking of ground beef. A 1996 survey indicated that 19.7% of the population consumed pink (undercooked) hamburger at some time during the previous 12 months (CDC, 1998a).

In its report of FoodNet for 1997, CDC stated: "In contrast with previous investigations, hamburgers eaten at fast food restaurants were not associated with infection, suggesting that recent changes in that industry may have reduced *E. coli* O157:H7 infections from that source" (CDC, 1998b). This is a conservative assessment because a review of the outbreaks reported each year by CDC shows no reported outbreaks from the larger fast food operations between 1993–2000. This verifies that the control measures adopted in those operations have been effective in managing the risk of *E. coli* O157:H7 in ground beef.

The improved controls in fast food operations do not appear to have carried through to other areas. A case-control study conducted at FoodNet sites has determined that undercooked ground beef continues to be a principal food source of *E. coli* O157:H7 infections (CDC, 1998b). Outbreaks have continued to occur in other food service establishments (e.g., restaurants, schools) and among consumers who prepare ground beef at home, on camping trips, or in other settings. Ground beef is the primary vehicle, not roasts, steaks, etc.

This information suggests that a continuing effort should be directed toward educating food handlers and consumers in proper handling and cooking of ground beef before serving. A goal should be established to reduce the percentage of consumers who consume rare ground beef from approximately 20% to some lower value. School systems and other food service establishments should consider additional training/education and other options (e.g., precooked beef products).

17.2.3.1 Survey Results from USDA-FSIS

The US Department of Agriculture (USDA)-Food Safety and Inspection Service (FSIS) established a sampling and testing program for ground beef in 1994 to:

- stimulate industry actions to reduce the presence of *E. coli* O157:H7 in raw ground beef (i.e., to encourage industry to institute and maintain effective control measures),
- encourage industry to sample and test raw ground beef routinely,
- find and remove from commerce product containing *E. coli* O157:H7, and
- expand the agency's information base and understanding in the control of *E. coli* O157:H7 (FSIS, 1994).

Results of the sampling and testing program are summarized in Table 17–2. The methods of sampling and analysis have been modified since 1995 to increase sensitivity of detection. During 1995–1997, a single 25 g sample was analyzed. Since the beginning of fiscal year 1998, five 65 g samples have been analyzed.

During the 1990s, industry implemented new control measures to reduce the occurrence of salmonellae and *E. coli* O157:H7 in ground beef. Due to the increased sensitivity of the methods used by FSIS, it is not possible to assess the effectiveness of changes implemented by industry or to determine whether the prevalence of *E. coli* O157:H7 in ground beef has, in fact, increased since the inception of the sampling program.

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Table 17–2 Results from the FSIS Sampling Program Beginning with Fiscal Year 1995

Fiscal Year	*No. Samples*	*No. Positive*	*% Positive*
1995*	5291	3	0.057
1996*	5326	4	0.075
1997*	5919	2	0.034
1998†	7529	14	0.19
1999†	8710	29	0.33
2000‡	>4,000	38	0.95

*25 g analytical units; †325 g analytical units, ‡325 g and improved isolation method (i.e., immunomagnetic beads to concentrate cells). The results for FY2000 are through August 11, 2000.

17.2.3.2 Data from Ground Beef Implicated in Illness and Lots Found Positive by USDA-FSIS

As ground beef has been implicated in outbreaks, samples from some implicated lots have been collected and analyzed. The ability to detect additional positive samples from across implicated lot(s) indicates a relatively high prevalence and concentration. In a few instances, a quantitative analysis was performed to determine the concentration of *E. coli* O157:H7. For example, in the 1993 outbreak that occurred in the northwestern US, frozen ground beef patties produced at a particular facility on November 19 and 20, 1992 were found positive. Positive samples were found in lots 4 and 9–17 in the production of November 19 and in lot 7 in the production of November 20. Quantitative analysis of some of the positive lots conducted by FSIS and CDC resulted in most probable number values in the range of 1–4 cells g^{-1}, with a single high value of 15 g^{-1} (FSIS, 1993).

Other evidence suggesting a relatively high prevalence and concentration of *E. coli* O157:H7 in certain lots of ground beef includes:

- large numbers of cases among consumers,
- multiple outbreaks involving consumers in different locations, and
- ability to detect *E. coli* O157:H7 with just a single sample from an implicated lot.

Follow-up sampling of positive lots of ground beef detected at retail stores has led to a positive sample from coarse ground beef used.

Data from the USDA-FSIS and lots implicated in outbreaks suggest that the vast majority of ground beef has a very low prevalence and concentration of *E. coli* O157:H7. In rare instances, a very small proportion of the lots contains a relatively high prevalence and concentration. It is because of this kind of skewed distribution in the number of bacteria that a log-normal distribution function is often used in microbiology. A hypothetical log-normal distribution of counts with a standard deviation would give the curve shown in Figure 17–1. Baseline studies on the numbers of bacteria in raw meat and poultry in the US and Canada provide further support to the general applicability of a log-normal distribution for the microbial population in these foods (FSIS, 1996; CFIA, 2000). When a log-normal distribution is assumed for these data, it is estimated that the standard deviation would be between 1.3 and 0.55. Figure 17–2 shows an estimated log-normal distribution (mean = 1.2, sigma =0.8) from counts obtained in the baseline study of the number of Biotype I *E. coli* in raw ground beef in the US compared to the

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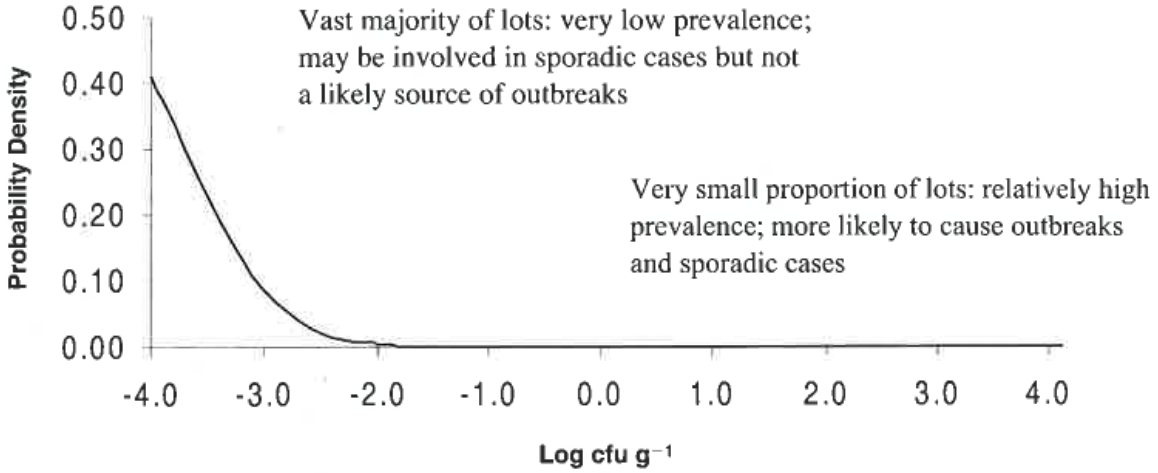


Figure 17–1 Illustration of the likely distribution in prevalence and concentration of *E. coli* O157:H7 in ground beef in North America.

hypothetical distribution for the counts of *E. coli* O157:H7 in raw ground beef. To consider the uses and limitations of sampling for *E. coli* O157:H7 in raw ground beef, we have assumed that the counts for this organism also have a log-normal distribution with a standard deviation value of 0.8, but a mean concentration < 1.2 g^{-1}. Although hypothetical, such a distribution of counts would be consistent with a prevalence of 1% positive in 325 g samples taken.

17.2.3.3 Lots with Low Prevalence and Concentration

The vast majority of ground beef has a very low prevalence and, presumably, low concentration of *E. coli* O157:H7. For example, the results of the FSIS sampling program suggest a background prevalence of about 1% or less when analyzing 325 g. This prevalence is likely influenced by the prevalence of *E. coli* O157:H7 that occurs in cattle at the time of slaughter and also reflects the level that may be normally achievable from slaugh-

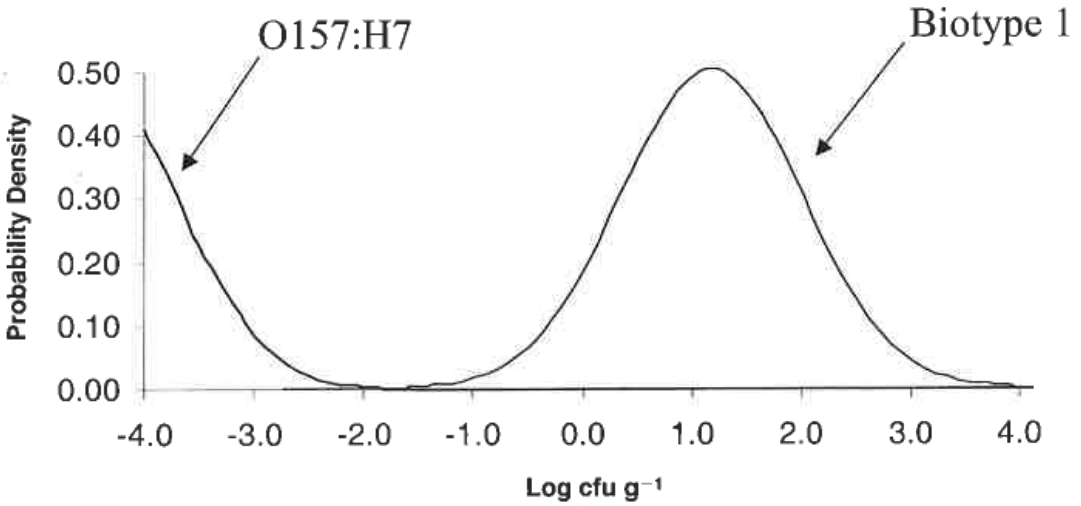


Figure 17–2 Comparison of hypothetical distribution in prevalence and concentration of *E. coli* O157:H to fitted distribution for *E. coli* Biotype I (mean = 1.2, sigma = 0.8) taken from the U.S. Nationwide Raw Beef Microbiological Survey Aug 1993–Mar 1994.

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ter to the manufacture of ground beef with existing technology. These lots have such a low prevalence of contamination that defective lots cannot be detected with any degree of confidence through routine microbiological testing. Possibly, these lots may be involved in sporadic cases, but seldom with outbreaks.

Considering the low prevalence, it is questionable that the FSIS sampling program alone, with 5,000–7,000 samples/year, would have a measurable impact on the number of cases/100,000/year attributable to *E. coli* O157:H7 in ground beef. While perhaps ineffective in ensuring consumer protection, the FSIS program does send a strong message to industry and consumers as to its expectations. This has been one factor that has resulted in the implementation of improved control measures in slaughtering operations.

It would be impractical to implement a routine sampling plan to detect and reject contaminated lots with a $\leq 1\%$ prevalence of contamination. For example, if the prevalence rate was 0.7%, the number (n) of samples required to detect the pathogen with a 95% probability would be 428 units. Even sampling to provide a 90% confidence level would require 329 sample units. Additional information describing the difficulty of detecting positive lots with low prevalence of contamination is evident in Table 17–3.

If the defect level is 0.5% and 30 sample units are tested, there is an 86% probability that all 30 samples will be found negative and the lot will be accepted. Even with 100 sample units, there is a 61% probability that all 100 samples will be found negative and the lot will be accepted. Clearly, microbiological sampling and testing are very ineffective for detecting lots with low prevalence of contamination.

17.2.3.4 Lots with Relatively High Prevalence

Experience indicates that a very small proportion of lots of ground beef have a relatively high prevalence (e.g., 5% or higher) and, presumably, higher concentration of cells (e.g., 1–10 g^{-1}). In these lots, it has been possible to find additional positive samples when resampled. Published information does not explain how these lots acquire a higher prevalence or concentration of *E. coli* O157:H7. It is strongly suspected that contamination results when trimmings from one or a few carcasses are introduced into the grinding process with other trimmings and cause a "comet-like" effect as described in Chapter 10 and Figure 10–4c. It is probable that these lots would more likely cause outbreaks as well as sporadic cases, if the product is undercooked or other foods are contaminated.

Due to the higher prevalence of contamination in these lots, it may be possible to apply a statistically valid sampling plan and, to the extent possible, exclude them from the mar-

Table 17–3 Probability of Accepting a Defective Lot with Indicated Proportion of Defective Sample Units

	No. of sample units			
% defective	*15*	*30*	*60*	*100*
0.1	0.99	0.97	0.94	0.90
0.5	0.93	0.86	0.74	0.61
1	0.86	0.74	0.55	0.37
2	0.74	0.55	0.30	0.13
5	0.46	0.21	0.05	0.01

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ket. Since it is not possible to anticipate which lots may be in this category, the intent of the sampling plan would be to detect them as they are produced.

17.2.4 Risk Characterization

The annual per capita consumption of ground beef in the US was estimated to be approximately 12 kg from 1982–1998 (AMI, 2000). If it is assumed that all the ground beef is consumed as hamburger patties weighing 125 g each, this would result in 96 servings/person/year. Since the total population in the US in 1998 was approximately 270 million, the total number of servings on a national basis would be about 26×10^9 servings per year. If the USDA survey data for FY 2000 are used, it can be assumed that the prevalence rate for *E. coli* O157:H7 in ground beef is about 1%. This prevalence rate was determined using five analytical units, each weighing 65 g. A positive result for any of the five analytic units was reported as a positive 325 g.

Data are not available for 125 g samples; however, for this example it will be assumed that the prevalence rate in 125 g samples is 0.7%. Given that assumption, it can be estimated that the number of raw hamburger patties containing *E. coli* O157:H7 each year is 26×10^7 (i.e., 1% of 26×10^9 servings). While a survey indicated that 19.7% of the population had consumed pink (undercooked) ground beef at some time during the previous 12 months, it is not likely that this occurred with each serving. For example, individuals purchasing hamburgers in fast food operations would very likely receive a hamburger that is well done and with no evidence of undercooking. This would significantly reduce the extent of exposure to undercooked hamburgers containing *E. coli* O157:H7. If it is assumed that undercooked hamburgers were consumed 5% of the time among the respondents of the survey, then, it can be estimated that the number of undercooked servings that contained *E. coli* O157:H7 before cooking would be about 26×10^5 [i.e., $5\% \times 19.7\% \times (26 \times 10^7)$]. If it is further assumed that the concentration of *E. coli* O157:H7 in the patties before cooking is 1 g^{-1} (H_0), then the number of cells would be 125/patty and their distribution within the patties would influence whether they are killed during cooking. It has been reported that an expected D value for *E. coli* O157:H7 in ground beef with 30.5% fat is 0.47 min at 62.8 °C (Line *et al.*, 1991). Cooking beef to this temperature typically yields a medium-rare (i.e., not raw) appearance. It is not likely that *E. coli* O157:H7 with an initial level of 1 g^{-1} would survive in a patty that is cooked to 62.8 °C unless, perhaps, all the cells are at the site of slowest heating within the patty. Thus, it may be possible for patties to appear undercooked (medium-rare), but have no viable cells remaining. As with many of the assumptions in this example, data are not available for the frequency of undercooking. Thus, it will be assumed for this example that 10% of the undercooked patties are insufficiently cooked to kill all the cells that are present. This leads to an estimate of approximately 26×10^4 patties/year potentially being consumed in the US that contain viable *E. coli* O157:H7.

The extent to which these patties would lead to illness would be influenced by many factors, in particular the susceptibility of the consumer. It is not likely that the most highly sensitive population, namely children less than five years of age and the elderly, would consume hamburger at a rate of 96 servings/year. In addition, these estimates assume that all the ground beef is consumed as patties. These estimates also ignore the fact that a significant portion of the patties are cooked in USDA inspected facilities and

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in fast food operations that apply control measures to ensure a minimum internal temperature of 70 °C.

17.3 RISK MANAGEMENT

17.3.1 Level of Consumer Protection

The exposure assessment revealed that about 25% of the *E. coli* O157:H7 outbreaks during 1982–1997 and 33% of illnesses were attributable to ground beef (FSIS, 1998). An estimate for sporadic cases is not available. Using those data, and assuming that there are 62,458 foodborne cases of *E. coli* O157:H7 per year, then the number of cases attributable to ground beef would be approximately 20,611 cases/year. An example of a public health goal for this food-pathogen combination would be to reduce or eliminate the number of cases attributable to ground beef. A 25% reduction in the number of cases attributed to ground beef, for example, would mean a reduction of 5,152 cases/year.

17.3.2 Establishing a Food Safety Objective

In this example, it is difficult to establish a clear relationship between the level of *E. coli* O157:H7 consumed and the probability of illness. However, outbreak data (AGA, 1994; Tarr, 1994) and risk estimates (Cassin *et al.*, 1998) suggest that fewer than 100, to as low as a dozen or so cells, can cause illness among consumers, particularly those at greater risk. Therefore, to establish a food safety objective (FSO) for this example, it is important for the value to be necessarily conservative to reflect the degree of uncertainty, the relatively low infective dose, and the severity of the illness. An example of an FSO would be:

The concentration of *E. coli* O157:H7 in raw ground beef shall not exceed 1 cfu 250 g^{-1}.

Since a concentration of 1 cfu 250 g^{-1} also can be expressed as -2.4 $\log_{10}$ cfu g^{-1}, the FSO also could be stated as the concentration of *E. coli* O157:H7 in raw ground beef shall not exceed -2.4 $\log_{10}$ cfu g^{-1}. The FSO is equivalent to no greater than 1 cell per two patties with each weighing 125 g, a common weight for commercially manufactured ground beef patties.

The proposed FSO should provide a margin of safety considering the thermal destruction that occurs even in undercooked patties. This FSO is only applicable to ground beef for sale in retail stores or for use in food service establishments. Ground beef for manufacturing products cooked in commercial establishments with Hazard Analysis Critical Control Point (HACCP) systems need not meet the proposed FSO because the required cooking processes have been validated to ensure destruction of at least 10^5 g^{-1} salmonellae or *E. coli* O157:H7.

17.4 CONTROL MEASURES

17.4.1 Good Hygienic Practices (GHP)/HACCP

A generic model HACCP plan has been developed for teaching the principles of HACCP to those involved in the manufacture of frozen ground beef patties (Bernard *et*

al., 1997). The document discusses the strengths and limitations of GHP and HACCP for control of enteric pathogens in ground beef and provides guidance that may facilitate meeting the FSO by manufacturers of ground beef.

17.4.2 Controlling Initial Number (H_0)

The only means to control the concentration of enteric pathogens in raw ground beef is through raw material selection. The options would be limited to (1) supplier assurance programs and (2) pretesting trimmings before use. In addition, maintaining an effective time-temperature control program is needed to prevent growth of *E. coli* O157:H7 on carcasses during chilling/cutting and through grinding/freezing the ground beef patties.

17.4.2.1 Control through Supplier Assurance Programs

Control through supplier assurance programs entails selecting suppliers who have implemented interventions to minimize carcass contamination (e.g., enclosing bung in plastic bag and tying, an improved method of hoof and hide removal, use of steam vacuum on areas likely to be contaminated) during the slaughtering process and/or to decontaminate carcasses (e.g., hot water or steam pasteurization, organic acid spray) at strategic steps in the slaughtering process. As described earlier, it is likely that these control measures can significantly reduce, but will not likely eliminate, the presence of enteric pathogens (Dorsa *et al.*, 1996; Dorsa, 1997; Castillo *et al.*, 1998; Nutsch *et al.*, 1998; Sofos & Smith, 1998; Sofos *et al.*, 1999; Bacon *et al.*, 2000).

Suppliers should be audited following the guidelines in Chapter 4 and the results used as a basis for approval. Familiarity with the current use of interventions and their effectiveness should be incorporated into the audit. In addition, certain interventions (e.g., steam pasteurization, hot water sprays) may have been validated to achieve a minimum level of reduction under specified conditions of operation.

17.4.2.2 Control through an Incoming Raw Materials Screening Program

Control through an incoming raw materials screening program consists of using microbiological tests of incoming raw materials to identify and select the better, more reliable suppliers and to eliminate suppliers who exercise less control of microbial quality (Bernard *et al.*, 1997; Eisel *et al.*, 1997; Scanga *et al.*, 2000). These tests could involve indicator microorganisms as a general measure of GHP and good manufacturing practices.

Trimmings to be used for ground beef could be pretested for *E. coli* O157:H7 by various sampling plans (AMSA, 1999; Scanga *et al.*, 2000). One option would be to have the supplier sample the trimmings and have them analyzed while the raw materials are in transit. Slaughtering operations that use their own in-house trimmings to manufacture frozen ground beef patties could sample the trimmings before grinding.

Producers of ground beef should consider how much reliance to place on the interventions employed by suppliers and whether it is necessary, or effective, to test for *E. coli* O157:H7. If testing is used as a control measure, then consideration must be given to testing raw materials (i.e., trimmings) or finished product (i.e., frozen patties).

To meet the required FSO through raw material selection, the concentration of *E. coli* O157:H7 in the trimmings would have to be controlled so the ground beef will meet the FSO (i.e., FSO = $-2.4 \log_{10}$ or not exceed 1 per 250 g). This can be expressed in the following simple equation (described fully in Chapter 3).

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$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$H_0 - 0 + 0 \leq -2.4$$

$$H_0 \leq -2.4$$

Thus, the initial concentration of *E. coli* O157:H7 in the frozen ground beef patties must be -2.4 $\log_{10}$ cfu g^{-1} and, if present, there must be no growth ($\Sigma I = 0$).

There has been only one report of beef with a concentration of *E. coli* O157:H7 as high as 1,000/g. That occurred in a very small operation (i.e., a locker plant) that processed individual animals for local customers (Todd *et al.*, 1988). Such operations would be less able to exercise control over the slaughtering/chilling/fabrication process. In larger commercial operations, however, lower numbers of *E. coli* O157:H7 in trimmings and, ultimately, in ground beef would be expected. This would reflect the fact that few carcasses would carry the pathogen and some dilution of the pathogen would occur as trimmings are mixed with the large quantities of negative product. For these reasons, it may be assumed that the concentration of *E. coli* O157:H7 in trimmings from these operations would not likely exceed 100 g^{-1}. Even in the outbreak that occurred in the northwestern US, the highest concentration detected was 15 g^{-1}. Therefore, it is reasonable to assume that the initial level is unlikely to exceed 100 g^{-1} (i.e., $H_0 = 2$).

17.4.3 Reducing Levels (ΣR)

If an initial concentration of 100 g^{-1} is assumed as a worst case, then a performance criterion can be established for the reduction necessary to achieve the FSO of -2.4 $\log_{10}$ cfu g^{-1} (1 cell per 250 g) at the time the patties are consumed. This can be expressed as follows:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$2 - \Sigma R + 0 \leq -2.4$$

$$\Sigma R \leq 4.4$$

Thus, the performance standard for cooking the frozen patties could be stated as:

a 4.4D reduction of *E. coli* O157:H7 in the coldest area of the patty.

If the initial level (H_0) can be controlled to a lower level (e.g., $H_0 = 1$), then the performance criterion could be met with a milder cooking process (e.g., $\Sigma R \leq 3.4$).

The only means available to the ground beef producer to ensure that the patties will be cooked sufficiently to meet the FSO in restaurants, institutions, hotels, and other commercial operations would be to provide cooking instructions. This also would be necessary for consumer package labeling, but it is less certain whether consumers follow these instructions. In some regions of the world, regulations specify minimum cooking temperatures for ground beef. In the US, the Food Code (FDA, 1999) recommends that ground beef be cooked to an internal temperature of 66 °C for 1 min, 68 °C for 15 s or 70 °C for < 1 s. These time-temperature relationships provide a 6.5D or greater reduction for salmonellae, a pathogen of comparable heat resistance to *E. coli* O157:H7. Many states have adopted these recommendations. Food service operations that comply with this requirement would be applying a validated cooking process that would exceed the above performance standard. One reason for the greater thermal destruction required in the Food Code is that a value of 1000 g^{-1} was assumed for the estimated initial concen-

tration of *Salmonella* and *E. coli* O157:H7 in ground beef ($H_0 = 3$), and a minimum 6D reduction was desired ($\Sigma R = 6$).

17.4.4 Options Involving Research and Education

Information from the above risk evaluation could lead to several additional risk management options. Examples could include:

- support research that may lead to on-farm control measures (e.g., competitive exclusion, vaccine, control of water supply for cattle). This option should be viewed as a long-term endeavor.
- support research that may lead to additional in-plant control measures to minimize contamination during slaughter and/or decontamination of carcasses.
- provide education to food handlers, particularly those in higher risk situations (e.g., non-fast food service establishments, homes), for proper handling and preparation of ground beef for serving.
- encourage the use of a thermometer and discourage reliance on appearance for estimating doneness when cooking ground beef.
- evaluate the barriers to acceptance of irradiation of ground beef and assess how they may be overcome.
- support research on new technologies to reduce the level of *E. coli* O157:H7 in ground beef while retaining acceptable quality.

17.5 ACCEPTANCE CRITERIA

17.5.1 Organoleptic Criteria

The presence of *E. coli* O157:H7 in raw ground beef cannot be assessed by organoleptic evaluation and, thus, meaningful organoleptic criteria cannot be established.

17.5.2 Chemical and Physical Criteria

The presence of *E. coli* O157:H7 in raw ground beef cannot be assessed by chemical or physical determinations and, thus, meaningful chemical or physical criteria cannot be established.

17.5.3 Microbiological Criteria

The following considers the merits of testing frozen ground beef patties to verify that the FSO has been met by the manufacturer.

While it may not be possible to detect with confidence lots with a low prevalence of contamination, it may be possible to detect some lots of higher prevalence that are more likely to be associated with outbreaks. Thus, one risk management option may be to implement a routine sampling program specifically intended to detect those lots of relatively higher prevalence and, perhaps, concentration. Rare as those lots may be, they are more likely to be associated with illness. It must be emphasized, however, that such a sampling and testing program cannot guarantee the safety of lots that test negative!

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The decision to test the frozen ground beef patties as a risk management option can be influenced by many factors, such as:

- the potential public health impact, particularly to young children, in the event *E. coli* O157:H7 is present.
- the intended customer (e.g., food service or home) and intended use (i.e., likelihood of undercooking).
- the effectiveness of product labeling and supporting education to reduce the likelihood of mishandling and undercooking.
- costs associated with illness and liability should product be implicated.

17.5.3.1 Choice of Sampling Plan

The sampling plans recommended in Chapter 8 consider risk to the consumer, including the effect certain microbial agents may have on certain sensitive populations. *E. coli* O157:H7 has been placed into a classification that requires the most stringent sampling plans (i.e., cases 13–15) and 15, 30, or 60 sample units from a lot.

The decision to select 15, 30, or 60 samples depends on whether the hazard would be expected to decrease, not change, or increase between when a food is sampled and when it is consumed (NAS-NRC, 1969; Foster, 1971; NRC, 1985; ICMSF, 1986).

E. coli O157:H7 cannot multiply in frozen ground beef patties; extended holding times above 7–8 °C are needed for even a 10-fold increase. Thus, case 15 does not apply.

Since cooking will kill *E. coli* O157:H7, this suggests that a sampling plan of $n = 15$, $c = 0$ (case 13) would be appropriate. However, approximately 20% of consumers continue to consume rare ground beef. While it would be expected that partial cooking may reduce the number of *E. coli* O157:H7, cooking to a rare state cannot be depended on to eliminate the hazard. This leads to a sampling plan of $n = 30$, $c = 0$ (case 14) as being appropriate for raw ground beef. Recovery of *E. coli* O157:H7 from frozen ground beef implicated in outbreaks is evidence that freezing cannot be relied upon to eliminate the pathogen, further supporting selection of case 14.

It is important to reemphasize the limitations of testing food for the purpose of detecting and eliminating positive lots. For example, even with the proposed sampling plan of $n = 30$, $c = 0$, there is a 21% probability of accepting a lot when the proportion of positive sample units throughout the lot is 5%. There is a 74% probability of accepting a lot when the proportion of positive sample units is 1% (see Table 17–3).

17.5.3.2 Lot

The National Academy of Sciences-National Research Council Salmonella Committee (NAS-NRC, 1969) defined a lot as:

- an identifiable and identified unit of production, distinguishable from other units, that has been packaged
- within a determined period of time
- without major interruptions of flow, shutdowns, or other changes (such as the use of different sources of raw materials) that could be expected to cause one portion of the lot to differ significantly in integrity from another and that is
- complete and
- accessible for inspection and testing.

The ICMSF has defined a lot as follows:

> In the commercial sense, a lot is a quantity of food supposedly produced under identical conditions, all packages of which would normally bear a lot number that identifies the production during a particular time interval, and usually from a particular line, retort, or other critical processing unit. Statistically, a lot is considered as a collection of units of a product from which a sample is drawn to determine acceptability of the lot (ICMSF, 1986).

In this example, the maximum size of a lot consists of all the ground beef produced on common equipment from cleanup to cleanup. Smaller lots could be established (e.g., hourly).

17.5.3.3 Sample and Analytical Units

A sample unit is a representative sample collected at random from a lot that is a small-scale replica of the lot itself and from which a smaller analytical unit may be drawn for analysis.

- The sample unit is one frozen patty.
- The analytical unit is 25 g.

Ideally, the sample units would be submitted to a certified laboratory and analyzed by an official method, or its equivalent, for *E. coli* O157:H7. The method can be adjusted for analysis of 15 analytical units into a single 375 g composite sample. Research has validated that up to fifteen 25 g analytical units of ground beef or trimmings can be composited without significant loss in *E. coli* O157:H7 detection sensitivity (Silliker & Nickelson, 1995). This permits testing at a more reasonable cost and makes it more practical to screen lots to detect those of higher prevalence. The statistical implications of the proposed sampling plan are discussed in the following section.

17.5.3.4 Disposition of Positive Lots

The definition of a lot, the amount of product in a lot, and means of disposition are important considerations in the disposition of a positive lot. In this example, a lot consists of all product produced on common equipment from cleanup to cleanup, including rework. Rework consists of deformed, broken, or underweight patties. Rework can be returned to the grinder or blender on a frequent basis during operation, with the portion remaining at the end of production being discarded or handled separately. None would be added into the next day's production. Possible risk management options for positive lots include diverting the ground beef for use in products to be cooked in a facility that has an effective control system (i.e., GHP, HACCP) to ensure proper handling and destruction of the pathogen. Cooking can provide a substantial margin of safety that *E. coli* O157:H7 will be killed. It is recommended, however, that such lots not be used for the manufacture of fermented meats or in high temperature-short time processes, such as for links, patties, or meatballs.

17.6 STATISTICAL IMPLICATIONS OF THE PROPOSED SAMPLING PLAN

One premise of this example is that sampling can be used to screen out some, but not all, lots that exceed the FSO. A major weakness in this premise is that contamination is

more likely to be heterogeneous as illustrated in Figures 10–4b and c. The following discussion assumes, however, that contamination is randomly distributed (i.e., log-normal distribution and standard deviation of 0.8).

The proposed sampling plan involves analysis of 25 g from each of 30 sample units from a lot. A negative result provides 95% confidence that the concentration of *E. coli* O157:H7 in the lot is no more than 1 cell per 250 g (NAS-NRC, 1969; Foster, 1971). In addition, there is a 95% probability that if sampling and testing were extended indefinitely, the positive units found would not exceed 10%, equivalent to a lot average of fewer than one cell in 250 g (NAS-NRC, 1969). The underlying principles for relating the performance of a given sampling plan are explained in Legan *et al.* (2001) and in Chapter 7.

The sampling plans originally proposed by the NAS (NAS-NRC, 1969) and the Interagency-Industry Committee (Foster, 1971) were intended to be applied to suspect lots of food. They were to be used to supplement, not replace, existing routine tests being performed by companies to assess the acceptability of their products. Some companies, however, have adopted the sampling plans for end-product testing where the conditions of operation warranted concern. Similarly, the ICMSF has recommended the use of the appropriate sampling plans as a means to assess incoming lots of food at port-of-entry when no history of the conditions of production and storage is known.

Experience with the foregoing sampling plans has been favorable. Rarely has a food been found to cause foodborne illness, such as salmonellosis, when a lot was sampled and found acceptable. Conversely, foods implicated in foodborne illness normally have been found positive with the sampling plans. For about 30 years, sampling plans involving 15, 30, and 60 sample units from a lot have been accepted and applied by both industry and certain control authorities.

While it may be possible to rationalize the use of 30 sample units for determining the acceptability of a lot, the definition of a lot and the procedure for how and when samples should be collected from a lot are more difficult to justify on a statistical basis. Admittedly, the proposal provides for sampling frequencies that consider the need for procedures to be reasonable in a commercial operation. Confounding the issue is the uncertain distribution of *E. coli* O157:H7 throughout an operating day from cleanup to cleanup. The following from The Committee on *Salmonella* provides some guidance (NAS-NRC, 1969) on this concern.

The matter of *Salmonella* control is complicated by the question of distribution of salmonellae when they do occur in a food product. If this defect is random, it is not controlled by time; i.e., there is an equal opportunity for contamination to occur at any stage of the operation. If, on the other hand, contamination was limited to a certain segment of time during processing, then the defect would not be randomly distributed throughout the lot. If distribution is random, regular sampling procedures will detect the organism; if nonrandom, there is virtually no assurance of control unless the regulatory nature of time is known.

As previously indicated, in sampling a lot, random sampling is recommended. A random sample is one in which any individual tested is as likely to detect contamination as any other. This does not mean that one sample at one given time gives a measure of control of finished product, but rather that selecting samples at random during processing gives information on the lot. It is important that the lot be so defined that the foregoing requirements are met (NAS-NRC, 1969).

In conclusion, the sampling plan proposed above may be useful for screening out lots with a high prevalence of *E. coli* O157:H7 that exceed the FSO (-2.4 $\log_{10}$ cfu g^{-1}). How-

Table 17–4 The Relationship between the Number of 25 g Samples That Would Need To Test Negative To Control a Given Concentration (See Also Figure 17–3)

No. of 25 g samples testing negative	*Prevalence (%) needed to detect positives at 95% probability*	*Log concentration per 25 g controlled at 95% probability*	*Concentration controlled at 95% probability*
60	4.8	−1.33	1/526 g
50	5.8	−1.26	1/455 g
40	7.2	−1.17	1/370 g
30	9.5	−1.05	1/278 g
25	11	−0.97	1/233 g
20	14	−0.87	1/185 g
15	18	−0.73	1/135 g
10	26	−0.52	1/83 g
5	45	−0.10	1/32 g
3	63	−0.27	1/13 g

ever, it is also true that the sampling plan will have a relatively poor ability to detect positive lots where the level of the hazard is not random or is much lower. Another way of explaining this is to consider the likely defect rates. When the mean count is around -2.4 $\log_{10}$ cfu g^{-1}, the defect rate would be around 10% (sigma 0.8). The current defect rate measured in the FSIS sampling program is closer to 1%, which would equate to a mean count of around -4.5 $\log_{10}$ cfu g^{-1}, assuming a similar standard deviation (see Table 17–4 and Figure 17–3). Hence, it is important to again reemphasize the limitations of testing

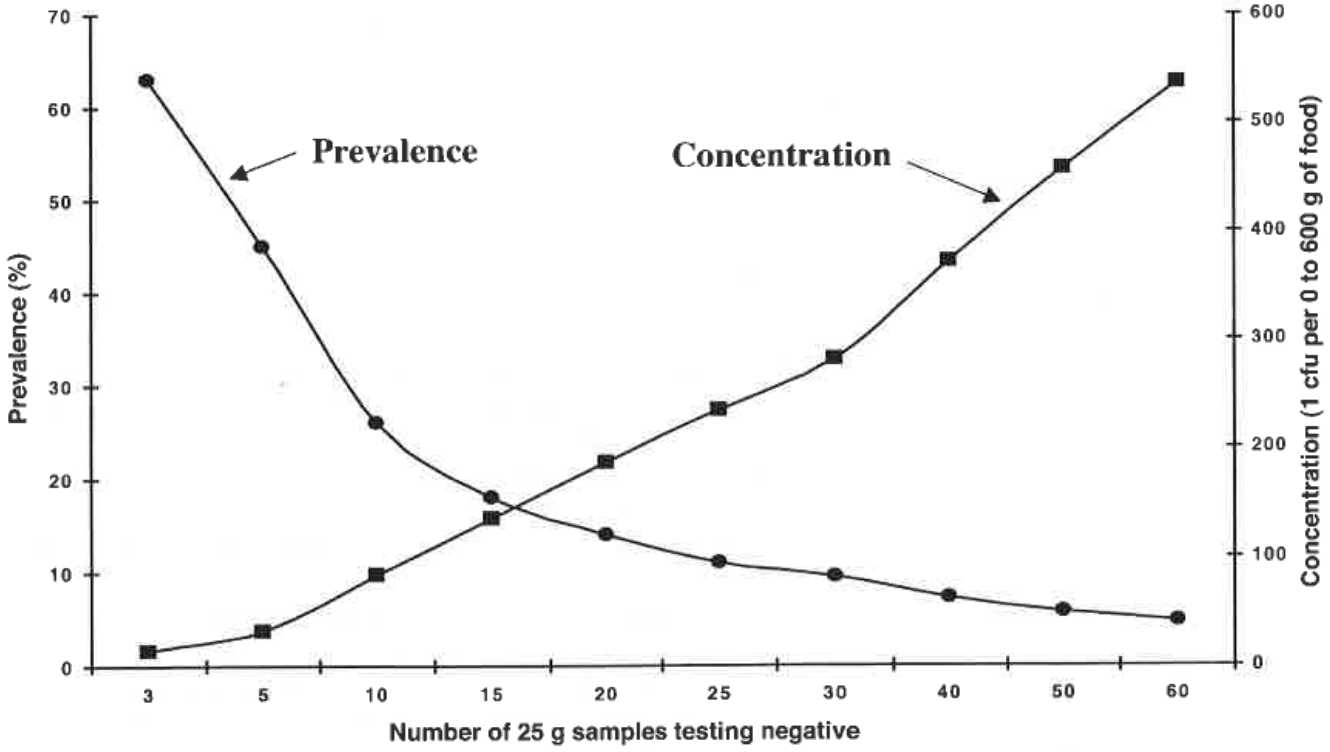


Figure 17–3 Relationship between the number of 25 g samples testing negative and the concentration and prevalence needed before the lot is rejected with 95% probability (assuming sigma = 0.8).

food for the purpose of detecting and eliminating positive lots with a low defect rate. Even with the proposed sampling plan of $n = 30$, $c = 0$, there is a 74% probability of acceptance when the proportion of positive sample units is 1%.

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MICROBIOLOGICAL TESTING IN FOOD SAFETY MANAGEMENT

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