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BACKGROUND PAPER

for the

JOINT FAO/WHO EXPERT CONSULTATION ON

Development of Practical Risk Management Strategies based on Microbiological Risk Assessment Outputs

Kiel, Germany, 3-7 April 2006

Case study: *Escherichia coli* O157:H7 in fresh raw ground beef

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This material is provided to facilitate transparency and international discussion and further development of microbiological risk management and food safety metrics. It should not in any situation be referenced as the opinion of FAO, WHO or the Codex Alimentarius.

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Note by Authors, July 2008.

This report describes quantitative risk assessments for *Escherichia coli* O157:H7 in fresh raw ground beef, and the outputs of risk assessment within the context of establishing new risk management metrics. We give an example of one approach to defining a range of performance objectives (PO) for beef trimmings and raw ground beef patties, and linking these with resulting expected probabilities of illness associated with the product when consumed, based on the assumptions of the quantitative risk model used to derive these examples.

Although the initial risk model that was used to generate the results in this study is probabilistic, the re-running of the model to calculate new risk estimates in this Working Draft (February 2006) were based on single point values for PO. Subsequent reflection and discussion at the FAO /WHO expert consultation for which this paper was prepared (Kiel, Germany, 3-7 April 2006) and a further consultation in Dublin, Ireland (September 4-7, 2006) would suggest that a more appropriate approach would have been to use distributions for the PO input values.

Consequently, the examples described here should be considered illustrative rather than definitive. The intent is to demonstrate the process of deriving risk metrics by considering the results of quantitative risk assessment, and the value of integrating risk assessment approaches together with GMP and HACCP programs to improve safety of the food supply.

Further work to expand on the findings in this document has recently commenced to improve the approach for using quantitative risk assessment outputs to establish practical food safety risk management metrics. Subsequently, the work presented in this current working draft document will then be updated as appropriate to finalize this report in the future.

For more in-depth discussion of these issues, the reader is referred to the following FAO/WHO expert consultation reports:

FAO/WHO. 2006. The use of microbial risk assessment outputs to develop practical risk management strategies: metrics to improve food safety. Report, Kiel, Germany, 3-7 April, 2006. *ftp://ftp.fao.org/ag/agn/food/kiel.pdf*.

Joint FAO/WHO meeting on enterohaemorrhagic *Escherichia coli* (EHEC) in raw meat and meat products: approaches for the provision of scientific advice (Dublin, Ireland, 4–7 September 2006). Report available Fall 2008 at: http://www.fao.org/ag/agn/jemra/ecoli_en.stm and http://www.who.int/foodsafety/micro/jemra/meetings/2005/en

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1   BACKGROUND

During the past ten years, considerable advancements have been achieved in the development of quantitative risk assessments for microbial pathogens in the food supply. More recently, new risk-based management concepts and approaches have been introduced, including the application of food safety objectives (FSOs), performance objectives (POs), and performance criteria (PCs) in order to relate public health goals to the level of stringency required for food safety measures and systems. From these parameters, food safety controls such as process criteria, product criteria and microbiological criteria may be derived. Risk assessments provide the basis for risk-based management options, however, guidelines, methods and practical examples of using risk assessment outputs toward these goals are lacking.

This report presents an example of how risk assessment information can be used to derive risk-based criteria for the management of enterohaemorrhagic *Escherichia coli* (EHEC) and specifically *Escherichia coli* O157:H7. This pathogen is recognized as a significant food borne hazard in many countries around the world. At the 36th Session of the Codex Committee on Food Hygiene(CCFH), a discussion paper on a risk profile of EHEC was introduced, which included identification of the commodities of concern based on international sources of information. Food vehicles implicated most frequently in outbreaks of EHEC infection have been raw or undercooked foods of bovine origin, especially undercooked hamburgers and unpasteurised milk (CCFH, 2005). For this present work, *E. coli* O157:H7 in ground beef was selected as a case study since quantitative risk assessments for the pathogen:matrix combination have been made available by different countries.

1.1   Resources

The following risk assessments were available to the working group:

Cassin, M. H., Lammerding, A. M., Todd, E. C. D., Ross, W., and McColl, R. S. 1998. Quantitative risk assessment for Escherichia coli O157:H7 in ground beef hamburgers. International Journal of Food Microbiology 41:21-44.

Duffy, G., Butler, F., Cummins, E., O'Brien, S., Nally, P., Carney, E., Henchion, M., Mahon, D., and Cowan, C. 2005. E. coli O157:H7 in minced beef produced in Ireland: A quantitative risk assessment, draft report. The National Food Centre, Teagasc, Ashtown, Dublin

Ebel, E., Schlosser, W., Kause, J., Orloski, K., Roberts, T., Narrod, C., Malcolm, S., Coleman, M., and Powell, M. 2004. Draft risk assessment of the public health impact of Escherichia coli O157:H7 in ground beef. Journal of Food Protection. 67:1991-1999 (summary of USDA-FSIS, 2001)..

Lammerding, A.M., Fazil, A., Paoli, G., Desmarchelier, P., and Vanderlinde, P. 1999. Shiga-toxin-producing E. coli in ground beef manufactured from Australian beef: Process improvement. Food Science Australia, Brisbane Laboratory. MSRC.002.

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

USDA-FSIS, 2001. Draft risk assessment of the public health impact of *Escherichia coli* O157:H7 in ground beef. http://www.fsis.usda.gov

In this document, the Irish Quantitative Risk Assessment (Duffy *et al*, 2005) is used as an example to generate a series of performance objectives and food safety objectives and show how these values influence the per serving risk and expected number of illnesses per 1 million servings. In order to achieve a desirable FSO and level of risk, the working group examined the feasibility of using microbiological testing as a risk-based management option. The background information for this example is based on a discussion paper (Tompkin and Bodnaruk, 1999) that later became a chapter (ICMSF, 2002) to discuss the merits of microbiological testing as a potential control measure to enhance the safety of ground beef. The working group example draws primarily on data from Ireland, the UK and the USA.

1.2   Risk Profile

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 enterohaemorrhagic *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* (Coia, 1998). Most EHEC isolates are acid tolerant, capable of surviving in acid foods and during passage through the stomach (Benjamin and Datta, 1995; Arnold and Kaspar, 1995; Leyer et al., 1995; Cheville et al., 1996).

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 enterohaemorrhagic *E. coli*, some of which may be more important in certain regions of the world than *E. coli* O157:H7 (WHO, 1997; Acheson, 2000).

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 centres. Direct contact with animals carrying the organism is also a recognized source of infection (WHO, 1997).

E. coli O157:H7 infection can result in moderate to severe disease, with most deaths occurring in children under 5 years of age and the elderly (AGA, 1994; Tarr, 1994; Duffy et al., 2005). Studies conducted in the USA suggest that from 13 to 27 cases of infection occur in the community for each confirmed case that is reported (Mead et al., 1999). Within the US FoodNet sites the annual laboratory confirmed case rate per 100,000 population was from 2.1 to 2.8 in the four years of 1996-99 (CDC, 2000). For the years 2000-2004 the incidence rate decreased from 2.9 to 0.9 cases per 100,000 population per year. From 1998 through 2003 the incidence rate for cases in Ireland ranged from 0.9 to 2.1 per 100,000 population per year (Duffy et al., 2005). Figure 1 illustrates the rising incidence of *E. coli* O157:H7 infection in three different regions of the world (CCFH, 2005). The higher incidence of disease in the USA has led to considerable research and policy changes by the USDA-FSIS and industry to break the chain of events leading to disease in that country.
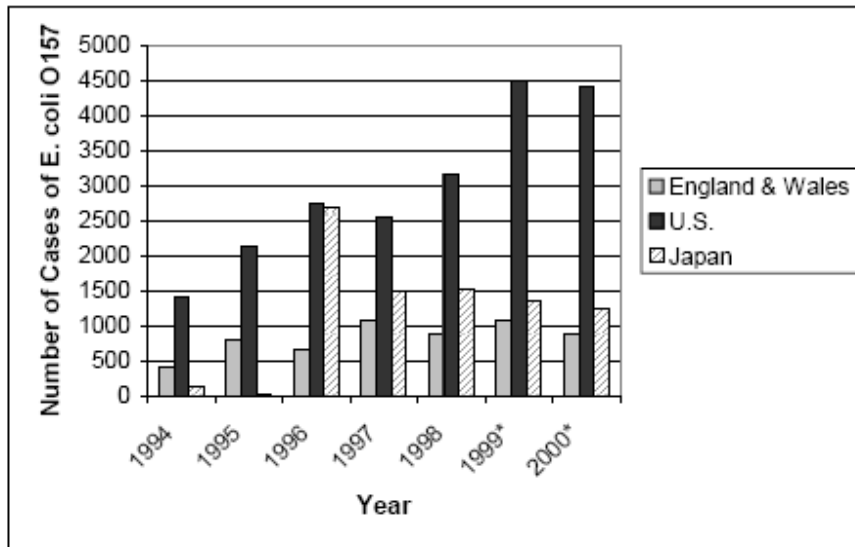
Figure 1. Number of reported cases of *E. coli* O157:H7 infection, U.S. (1994- 2000)[a], England and Wales (1994-2000)[b], and Japan (1996-2000)[c] (CCFH, 2005).

      a) CDC, NNDSS; Cases include suspect and confirmed human isolations.

      b) PHLS Laboratory of Enteric Pathogens; Cases include only isolates, obtained from stool samples, that are submitted to PHLS from laboratories in England and Wales. They are confirmed, serotyped, phage typed and VT typed at PHLS.

      c) Ministry of Health and Welfare, National Epidemiological Surveillance of Infectious Diseases; Cases are restricted to those with stool samples that have been culture confirmed and include all O157 serotypes.

The time to onset of symptoms following exposure ranges from 3 to 9 days with an average of 4. The duration of illness ranges from 2 to 9 days, however, with complications the illness may last many months and lead to permanent damage or even death. Others have reported the incubation period to be 1- 14 days with an illness duration of 5-7 days (Duffy et al., 2005). Symptoms may include haemorrhagic colitis: grossly bloody diarrhoea, severe abdominal pain, vomiting, but no fever; haemolytic uremic syndrome (HUS): prodrome of bloody diarrhoea, 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 develop the haemolytic uremic syndrome (HUS), characterized by acute renal failure, haemolytic anaemia, and thrombocytopenia that 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 5 years of age per year (Mahon et al, 1997). Risk factors associated with progression to HUS include: young age, long duration of diarrhoea, elevated leukocyte count and proteinuria (Tserenpuntsag et al., 2005)

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 5 years of age) (Mahon et al., 1997). In the 1993 north-western USA outbreak involving undercooked hamburgers it was estimated that as few as a dozen cells may have caused illness among children (Tarr, 1994).

Ground beef is of considerable importance to international trade. Ground beef is consumed in the form of hamburger and as a major ingredient in a variety of foods. In Europe ground beef can be distributed \as either a fresh refrigerated or a frozen product to consumers through retail outlets. In the USA ground beef is distributed primarily in a fresh, refrigerated state. Throughout much of the world ground beef is distributed to fast food restaurants as frozen patties. For the performance objective examples developed in this document, the working group will base its estimates on ground beef distributed as a fresh, refrigerated product.

In general, *E. coli* O157:H7 is deposited on the surface of beef carcasses during the slaughtering process. After chilling the carcasses are cut into larger portions for sale as bone-in or boneless beef cuts (e.g., round, loin, rib, chuck). During this 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
beef to other ready-to-eat foods also has occurred.

It is difficult to compare data from different countries due to the use of different methods of sampling/reporting. However, a WHO summary indicates that *E. coli* 0157: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% (WHO, 1997). Illnesses and mortality associated with contaminated ground beef, and other food commodities, are reported in countries worldwide (CCFH, 2005).

1.3   Current Legislation

Microbial criteria for Enterobacteriaceae and *E. coli* (Biotype 1) exist in most countries for raw beef, but do not specifically address *E. coli* O157:H7 or other STEC/EHEC serotypes. In the USA, since 1994, *E .coli* O157:H7 is considered an adulterant in raw beef products destined to be consumed in the form of ground beef or other non-intact (i.e., not steak or roast) products. Production lots of manufacturing trimmings or ground beef represented by a sample positive for *E. coli* O157:H7 cannot be sold for use as raw ground beef. Such positive product either must be manufactured into another product that receives a lethal treatment sufficient to destroy the pathogen (i.e., a ready-to-eat product such as cooked beef), or the product must be destroyed.

The US Food Code (FDA, 1999) recommends that ground beef be cooked to an internal temperature of 66°C for 1 minute, 68°C for 15 seconds or 70°C for less than 1 second. These time-temperatures will provide a 5.0 D or greater reduction for salmonellae in comminuted meat such as ground beef, a pathogen of comparable heat resistance to *E. coli* O157:H7. Many U.S. states have adopted this requirement. The U.S. regulatory requirements for cooked ground beef patties currently require that ground beef be cooked to a combination of time and temperature to achieve at least a 5-D reduction for both *Salmonella* and *E. coli* O157:H7 (i.e., 68.3 $^{\circ}$C for 16 seconds).

In attempts to minimize carcass contamination during slaughter operations, Ireland/the EU have mandated clean hide policies.

2   PROCESS DESCRIPTION

Figure 2 shows a general flow diagram for the production, distribution and preparation of fresh refrigerated ground beef (also referred to as hamburger, beef patties, minced beef, or beef burgers).

2.1   E. coli O157:H7 in the Farm-to-fork food chain and implications for control

2.1.1   On-farm

The source of *E. coli* O157:H7 on beef carcasses is the faeces on the hide and digestive tract content contained in the intestines of the cattle being slaughtered. Prevalence among cattle being held for slaughter is similar to, or 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 faeces 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 US slaughtering plants to be actively shedding *E. coli* O157:H7 or nonmotile *E. coli* O157 in their faeces during July and August, the months of highest prevalence. Eleven percent of the hide surfaces also were positive (Elder et al., 2000). More recent studies using improved methodologies suggest that the hides of cattle are the primary source of pathogens that contaminate carcasses (Koohmaraie et al., 2005)

Studies have shown that colonization of cattle is of short duration (1-2 months) with long-term carriers not having 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. The sporadic nature of colonization and shedding, and the apparent low with-in herd prevalence suggest that frequent and repeated testing is necessary to determine the status of herds and animals within the herds.

Contamination routes for and the population dynamics of *E. coli* O157:H7 on farms are currently unclear, limiting interventions and control options to those recommended within general guidelines for hygienic practices, quality assurance programs and/or application of HACCP principles to the extent possible (CCFH, 2005). Types of feed, feeding regimes, and administration of probiotics or vaccines to animals are examples of potential interventions that remain to be verified for effectiveness, and/or require further research, but which in the longer term may contribute to elimination of the pathogen.

Stress and long periods of transport, whether to farms, feedlots or the slaughterhouse, increase faecal shedding of EHEC. Efforts to limit stress of cattle prior to transport should be used to reduce shedding of EHEC upon arrival of the destination.
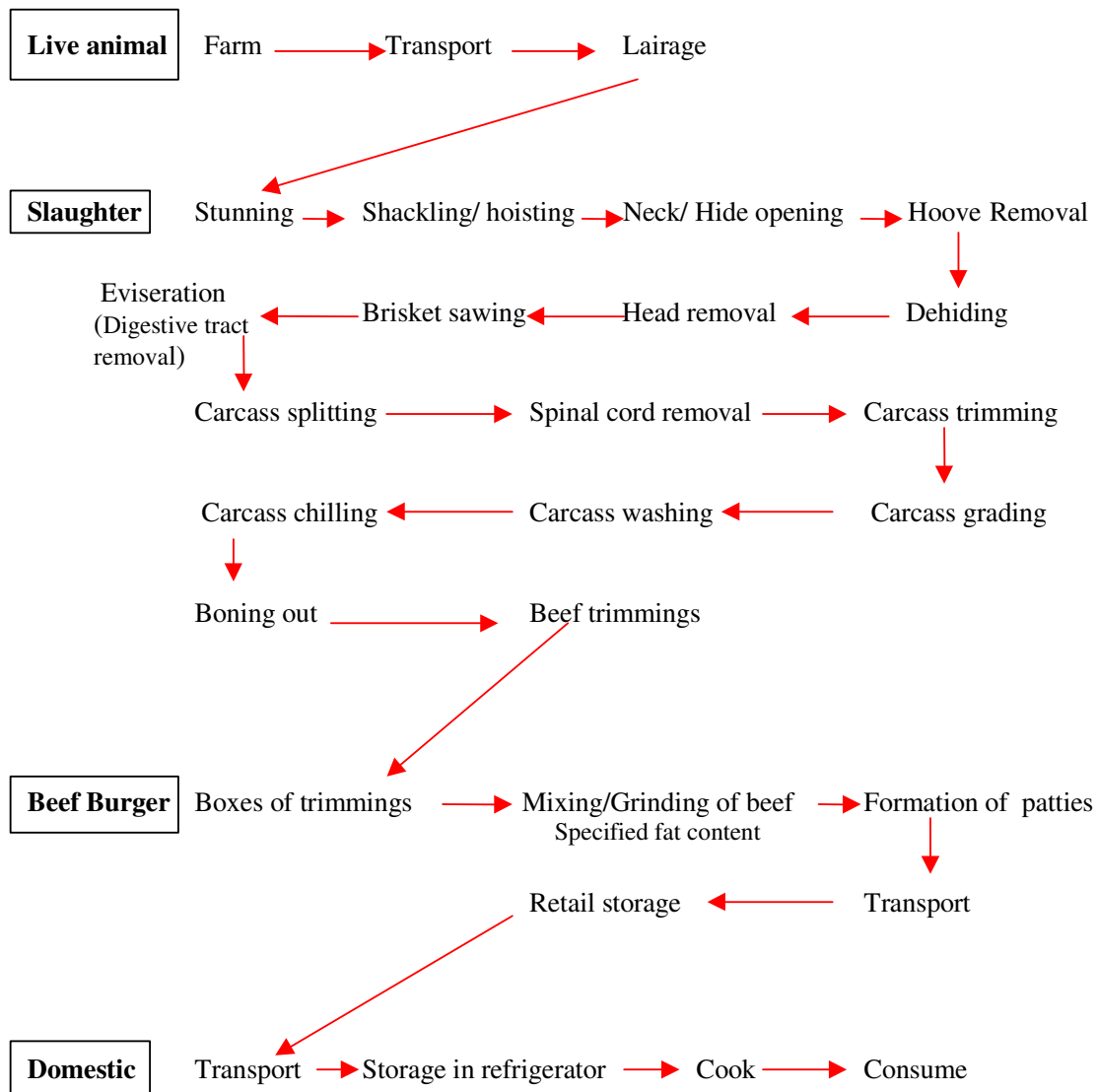
Figure 2: Flow diagram for the production of fresh beef burgers/patties

2.1.2 Slaughterhouse

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/cutting operation and contaminated subsequent lots of beef.

Technology is currently available that can:
- decontaminate hides prior to removal,
- minimize carcass contamination during the slaughtering process,
- reduce the likelihood of microbial attachment to exposed tissues, and

- decontaminate carcasses using technologies such as steam, hot water or organic acid sprays prior to and after chilling.

Many countries prohibit the use of some of these technologies (e.g., organic acid sprays). Collectively, the above control measures can significantly reduce, but not eliminate, the likely presence of enteric pathogens on raw beef. Where permitted, 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 and Smith, 1998; Sofos, Belk and Smith, 1999; Bacon et al., 2000, Koohmaraie et al., 2005).

It is reasonable to assume that when present, *E. coli* O157:H7 is on the surface of carcasses, not in internal tissues of intact muscle that normally is protected from surface contamination during slaughter. 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 cutting because the lower temperature limit for multiplication of *E. coli* O157:H7 is 7-8ºC (ICMSF, 1996). Furthermore, estimates for growth under optimum laboratory conditions in broth indicate that:
- at 10ºC the time to increase 10–fold is estimated to be 73 hr and
- at 15ºC the time to increase 10-fold is estimated to be 25 hr (Buchanan and Whiting, 1996).

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

2.1.3   Retail

Improper display temperatures may allow growth of the pathogen; improper handling of unpackaged meat, or leakage from wrapped packages may lead to cross-contamination. Hygienic practices and HACCP systems are relied upon to maintain control.

2.1.4   Consumer

During 1982-97 ground beef was the likely vehicle of infection for 25% of the *E. coli* O157:H7 outbreaks and 33% of illnesses associated with outbreaks in the USA. During 1994–97 a declining trend occurred with fewer illnesses being associated with outbreaks attributable to ground beef. The percent of illnesses was 25.8, 15.4, 4.3, and 6.7% during 1994 through 1997, respectively (USDA-FSIS, 1998). An estimate for the number of sporadic cases attributable to ground beef was not available.

Case-control studies (Table 1) have indicated ground beef as an important risk factor for EHEC infection (CCFH, 2005).

Epidemiologic data for outbreaks reported each year by the U.S. Centers for Disease Control and Prevention (CDC) indicate the risk of *E. coli* O157:H7 from beef continues 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 US survey indicated that 19.7% of the population consumed pink (undercooked) hamburger at some time during the previous 12 months (CDCa, 1998).

Table 1: Case-control studies implicating ground beef as a vehicle of infection with Enterohaemorrhagic *Escherichia coli* (EHEC).

Study type	Findings
Case-control, sporadic illness	Consumption of ground beef with pink centre had 34% population attributable risk
Case-control, sporadic illness	45% of ill persons consumed ground beef with pink centre in the preceding week while 33% of controls did the same
Case-control, sporadic illness	Ground beef with pink centre was a statistically significant risk factor while consumption of just ground beef was not
Prospective study	Rare ground beef was consumed more often by ill persons than healthy persons
Case-control, sporadic illness	Consumption of undercooked ground beef had an attributable risk factor of 17%

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"(CDCb, 1998). This is a conservative assessment because there were no reported outbreaks from the larger fast food operations between 1993 and 2000. This verifies that the control measures adopted by those operations, i.e., specified cooking regimes and hygienic practices, 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 of the food chain. A case-control study conducted at FoodNet sites has determined undercooked ground beef continues to be a principle food source of *E. coli* O157:H7 infections (CDCb, 1998). 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 other settings. Ground beef is the primary vehicle; not roasts, steaks and similar beef cuts, although needle tenderization has been associated with at least three recent outbreaks due to *E. coli* O157:H7 among consumers. However, in 2004, CDC reported that the incidence of *E. coli* O157:H7 decreased by 42% from 1996-2004 and that for the first time since tracking human illness for this pathogen, the incidence deceased below the goal of no more than 1.0 cases per 100,000 to 0.9 cases (CDC, 2005).

This information suggests 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. School systems and other food service establishments should consider additional training/education of food handlers and other options (e.g., using precooked beef products).

3 AVAILABLE RISK ASSESSMENTS & OTHER RELEVANT INFORMATION

3.1 Cassin et al., 1998

Model description: A farm-to-fork process risk model (PRM) for the production of beef trim in 5 kg packs for grinding at retail, and final preparation and consumption of hamburgers in the home.

Initial data inputs: Prevalence of *E. coli* O157:H7 in cattle: 0-1.6 % (published data from survey years 1984 – 1994 in Canada and the USA); estimated distribution of numbers of *E. coli* O157:H7 shed in faeces of positive animals based on one study of 13 animals, ranging from < 2.0 – 5.0 $\log_{10}$ CFU/g (Zhao et al., 1995); distribution of hamburger cooking practices based on US survey data indicating approximately 20% of consumers prepared rare or medium rare, corresponding to mean internal temperatures of 58.6°C or less.

Key assumptions: A "carcass contamination factor" was derived from data on concentration of Biotype 1 *E. coli* counts in faeces and resulting counts on carcass surfaces after dehiding. The reduction of counts of *E. coli* O157:H7 on the carcass due to decontamination treatments was aggregated into a single parameter and assumed to be a 1- 2.5 log reduction; retail/home storage temperatures distribution assumed minimum 4ºC, mode 10ºC to maximum of 15ºC. Dose-response model was a modification of that based on *Shigella* feeding studies. Probability of illness for susceptible populations was assumed to be the same as the general population, however, the model considered increased severity of outcomes in children and the elderly (i.e., HUS and mortality) based on epidemiological data.

Intermediate outputs: Mean prevalence of contaminated retail packages (300 – 1000g) of fresh ground beef: 2.9%. Predicted number of O157:H7 in contaminated packages: 87% < 10 CFU; 90% < 1000 CFU/package.

Risk estimate: Average probability of illness from a single meal: 5.1 x 10^{-5} (range 10^{-2} to 10^{-22}).

Key findings: Importance analysis ranked the following factors as the most important predictors of risk: Concentration of pathogen in faeces; host susceptibility; carcass contamination factor; cooking preference; retail storage temperature; reductions due to decontamination during primary processing; growth during processing.

Potential targets for risk management were assessed using hypothetical assumptions for effectiveness of interventions: (i) pre-slaughter treatment of cattle to reduce maximum concentration pathogen shed in faeces such that levels higher than 4 log CFU/g were eliminated resulted in a 25 % reduction of risk; (ii) retail storage temperature mode reduced to 8ºC from 10ºC resulted in an 80% reduction of risk; (iii) an information campaign targeting consumers resulting in a shift from 18.6% consuming rare or medium rare ground beef to 12% resulted in a 16% reduction of number of illnesses.

3.2 Lammerding et al., 1999

Model description and data inputs: Adapted PRM model of Cassin et al. (1998) substituting data for prevalence of STEC (Shiga-toxin (Stx)-producing *E. coli*) in Australian cattle (35.4 – 53.4%) and a modification to account for the proportion of 'potentially pathogenic' STEC based on the presence of

virulence markers Stx1, Stx2, *eae* gene and the EHEC plasmid. Weekend chilling for a portion of carcasses was also considered and assumed to allow greater proliferation of the pathogen than overnight chilling.

Risk estimate: Expected probability of illness was 6.4 x 10^{-4} per serving for adults and 4.6 x 10^{-4} for a child under the age of 5 years.

Key observations: Scenario analysis showed that use of hot water decontamination (expected 1- to 4-log reduction in STEC numbers on carcasses) resulted in a predicted 99.7% reduction in risk of illness; irradiation of de-boned and frozen trimmings with 1 kGy (expected reduction of STEC numbers of 1.3 to 1.8- logs) a 97% reduction of illnesses; eliminating or implementing stricter temperature controls for over-weekend chilling such that the maximum proliferation limited to the same as overnight chilling resulted in a 20% decrease in risk.

3.3   USDA-FSIS, 2001 and Ebel et al., 2004

Model description: Exposure assessment considers farm, slaughter, production of trim for grinding, and preparation factors that influence likelihood of consumption in ground beef servings; multiple 2,000-lb (909.1 kg) combo bins or 60lb (27.27 kg) boxes produced for grinding; ground beef servings as patties, meatballs and meatloaf.

Initial data inputs: *E. coli* O157-H7 prevalence data published 1994 – 2001, adjusted to estimate true prevalence. Breeding (cull) cattle: herd mean 63%; within herd 3% during low prevalence season (October – May), 4% during high prevalence season (June – Sept). Feedlot (beef) cattle: 88% herd prevalence; within lot 9% and 22% animal prevalence during low and high prevalence seasons, respectively. Carcass pathogen densities based on 1994 baseline data: positive carcasses ranged from < 0.03 to 3.0 CFU/cm^2. Fresh ground beef prevalence predicted by model adjusted by 'anchoring' to actual survey data. Cooking practices were based on US survey data (approximately 20% prepared rare or medium rare).

Key assumptions: Collective effect of interventions for decontamination (1st after dehiding: trim/wash/vacuum; 2nd final wash: (hot water, steam pasteurization) estimated to be 1.5 log reduction; dose-response function derived from (i) epidemiological data for *E. coli* O157:H7 illnesses; (ii) predicted number of contaminated ground beef servings; and (iii) bounded by upper and lower dose-response curves from surrogate pathogens *Shigella dysentery* and enteropathogenic *E. coli* (EPEC), respectively (Powell et al., 2000).

Intermediate outputs: The combo bins of manufacturing trim derived from dairy cattle, an estimated average of 6 and 8 percent of combo bins contained at least one or more *E. coli* O157:H7 organisms during the low and high prevalence season, respectively (Figure 3). Similarly, for the combo bins of manufacturing trim derived from steers and heifers, an estimated average of 23 and 43 percent of combo bins contained at least one or more *E. coli* O157:H7 organisms during the low and high prevalence season, respectively (Figure 4). Estimates also were made on the likely counts of *E. coli* O157:H7 in combo bins of manufacturing trim, ranging from 2 and 3 organisms in trim from dairy cattle in the low and high prevalence season, respectively. For combo bins of manufacturing trim from steers and heifers, the likely counts of *E. coli* O157:H7 organisms ranged from 13 and 41 organisms in the low and high prevalence season, respectively. For the combo bins of ground beef composed of combinations of manufacturing trim from both dairy cattle and steers and heifers in order to attain a specified fat content in the resulting finely comminuted beef, an average of 68 and 86 percent of combo bins contained at least 1 or more *E. coli* O157:H7 organisms during the low and high prevalence season, respectively (Figure. 5). The model predicted that 0.018% of prepared servings consumed during June through September (high prevalence

season) and 0.007% of servings consumed during the remainder of the year are contaminated with one or more *E. coli* O157:H7.
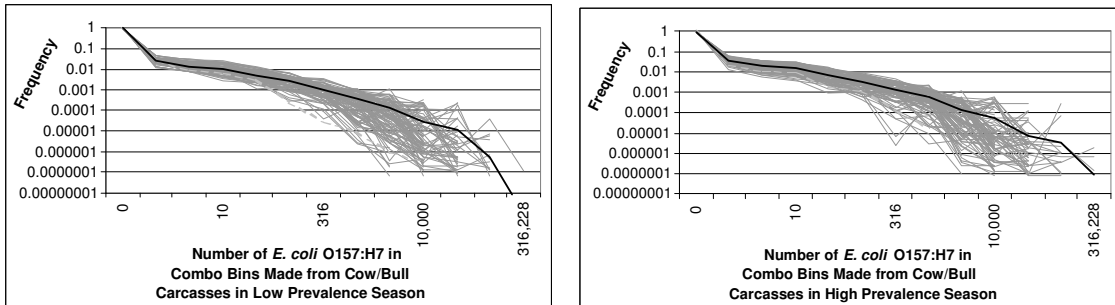
Figure 3: Comparison of seasonal distributions for number of *E. coli* O157:H7 in combo bins constructed from the slaughter of breeding (cow/bull) cattle. Dark lines are the mean distributions for each season.
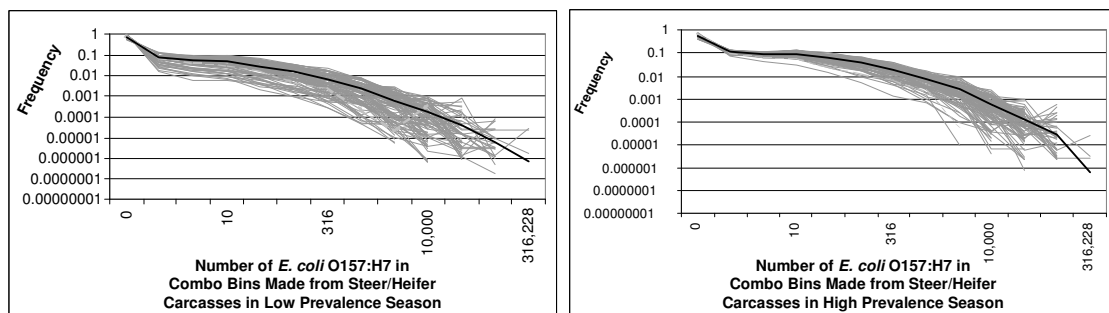
Figure 4: Comparison of seasonal distributions for number of *E. coli* O157:H7 in combo bins constructed from the slaughter of feedlot (steer/heifer) cattle. Dark lines are the mean distributions for each season.
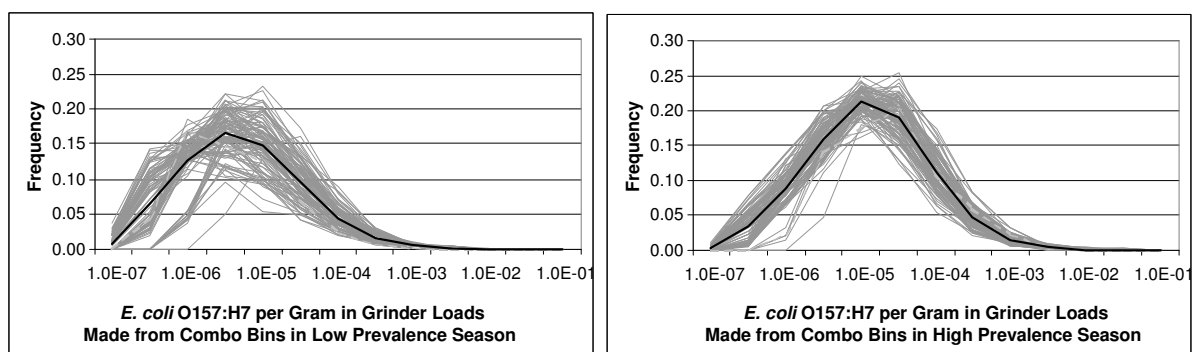
Figure 5: Frequency of ground beef contamination in contaminated grinder loads made from 2,000-pound combo bins in low and high prevalence seasons. Grinder loads that are not contaminated are not shown in this chart. The mean grinder load distribution is represented by the dark line.

Risk estimate: Annual US population risk estimate: nearly 1 illness in each 1 million (9.6×10^{-7}) servings of ground beef consumed. When seasonality was considered, there was a 3 fold higher risk in June – Sept.: 1 in every 600,000 servings (1.7×10^{-6}) vs. 1 in 1.6 million servings (6.0×10^{-7}) during Oct – May. For children age 0-5 years, the risk was estimated to be 2.5-times higher than for older consumers; although fewer exposures are expected, that fact that they are at greater susceptibility was accounted for by using the upper bound of the dose-response curve.

Key findings: Various scenarios were modelled and indicated that the likelihood of finding *E. coli* O157:H7 through testing of manufacturing trim was substantively higher, by approximately a 5-fold difference, than through testing of ground beef alone. Importance analysis ranked the following factors as the most important predictors: the occurrence and extent of *E. coli* O157:H7 contamination in beef trim and subsequent grinder loads was most influenced by (i) feedlot and within-feedlot prevalence; (ii) probability of carcass contamination following dehiding; (iii) amount of carcass contaminated; (iv) effectiveness of decontamination procedures and (iv) carcass chilling. The effect of these factors on the occurrence and extent of contamination varied by season and type of cattle (feedlot herd or breeding herd).

Occurrence and extent of *E. coli* O157:H7 contamination in cooked ground beef was in addition influenced by (i) proportion of ground beef that is frozen; (ii) the maximum population density of *E. coli* O157:H7 in ground beef; (iii) storage temperatures and (iv) cooking. The US population risk is influenced more by number of contaminated servings than number of *E. coli* O157:H7 per serving.

3.4   Nauta et al., 2001

Model description: Risk was estimated for the consumption of steak tartare patties, a lean (<10% fat) ground beef product typically eaten raw or partially raw in The Netherlands. The model considered three routes of exposure that encompass different slaughter practices and subsequent processing (industrial and traditional, differentiating size of slaughter operation and traditional butcher versus industrial preparation of product); three preparation styles of tartare patties (raw, medium and well done); three age classes of consumers: 1-4 years, 5-14 years, and 15+ years of age.

Initial data inputs: Overall average animal level prevalence of *E. coli* O157:H7 in Dutch cattle used for tartare estimated to be 1%. (O*n the farm: 0-19 % and 0-25% for dairy cattle and veal calves, respectively; at the animal level 0-9% and 0-61% for negative and positive tested farms for dairy cattle; for veal bulls, the animal level varies from 10-36% for farms found positive. Prevalence at herd and animal level at slaughterhouses also considered).* Concentration of pathogen in faeces of shedding animals was based on studies of Zhao et al. (1995). Tartare was consumed raw 2.6% of the time and prepared (medium or well done) by remainder of consumers.

Key Assumptions: Expert elicitation was used to estimate several parameters, including extent of faecal contamination of carcasses and percentage of patties thoroughly heated (20%). Given typical storage times and temperatures at retail and in the home, growth of pathogen in steak tartare was not expected to be an important factor. The dose-response model was based on data from a 1996 outbreak in Japan and resulted in a dose-response similar to that for feed trials for *Shigella.* The model derived for this study predicts the highest probability of illness per single cell ingested compared with alternate models (Table 2).

Table 2: A comparison of dose-response models for STEC O157:H7 (adapted from Nauta et al., 2001)

Model	Bacterial spp.	Probability of illness per single cell *	Reference
Exponential	E. coli O157:H7	0.005	Nauta et al. 2001
Beta-Poisson	*Shigella* and *S. flexneri*	0.001	Cassin et al., 1998
Beta-Poisson	*S. dysenteriae* and enteropathogenic *E. coli*	0.00003	Powell et al. 2000; USDA-FSIS, 2001; Ebel et al., 2004; Duffy et al., 2005

* Probabilities given for the Beta-Poisson model are mean values of the underlying Beta distribution.

Intermediate outputs: For industrial ground beef (i.e., large volumes processed), the model predicted that the prevalence of contaminated batches is higher than that prepared in traditional facilities, where meat of only one or a few carcasses is used per batch. However, at the level of raw steak tartare patties (unit sizes), prevalence's are almost equal. Pathogen numbers in contaminated product were smaller in industrially produced patties, a result of diluting contamination throughout large volumes of uncontaminated meat. Overall, the exposure model predicts 0.3% of raw steak tartare patties are contaminated; about 64% of positive patties contain only 1 CFU, and only 7% contain more than 10 CFU. The model assumption was that 1 CFU per 100g is detected. However Dutch national survey data for the product indicated 1.2% of raw patties positive (1/82 samples), thus the realistic sensitivity of testing is closer to10 CFU/100g and the assumption regarding detection in the model was an underestimate.

Risk Estimation: The predicted number of illnesses associated with the consumption of steak tartare in The Netherlands is 1284 cases per year, an incidence rate of 8 per 100,000 persons. By comparison, the incidence rate of STEC O157 illnesses from all sources, based on epidemiological data, is estimated to be 13 cases per 100,000. The authors suggest that the model prediction may be overestimating the number of illnesses associated with the product, possibly driven by the dose-response model used which predicts a higher probability of illness than models used by other authors. Using an alternate dose-response model (Powell et al.,2000), only 17 cases per year were predicted from the consumption of steak tartare.

Key findings: Scenario analysis was used to identify the important parameters of the model and model assumptions. Effects on the risk estimate of uncertainty in farm prevalence and concentration of the pathogen in faeces were large, as were effects of growth/inactivation on carcasses. Based on the model and expertise, the factors that may decrease risk associated with the product are: lowering prevalence and concentration of *E. coli* O157 in cattle, improved hygiene at slaughter or by increased frequency of industrial processing. Product control by monitoring at retail did not appear to be practical given low prevalence and concentrations, and growth during storage unlikely. Intervention at the consumer level, using an information campaign to influence preparation practices, was not part of the risk assessment model. However, this aspect is addressed through professional opinions from communication experts on potential effectiveness of an information campaign. It was concluded that this strategy would be unlikely to contribute to risk reduction for the product.

3.5   Duffy et al., 2005

Model description: The model considered slaughter and the potential contamination of carcasses in the abattoir with *E. coli* O157:H7, taking account of the impact various slaughtering processes may have on the distribution of the bacteria: preparation of beef burgers focused on processing of beef trimmings (from one or more 27.5 kg boxes of beef trimmings) into beef burgers; retail handling practices and their effects on bacterial numbers; and finally domestic storage/ preparation and cooking were considered. In the developed model, variability and uncertainty in the input parameters were incorporated by the construction of a second order model by means of probabilistic distributions.

Data inputs: Data inputs on the prevalence and concentration of *E. coli* O157:H7 in the Irish beef chain were based on a number of microbiological surveys on the pathogen at key points in the chain including bovine faeces (McEvoy et al., 2003), bovine hide (O'Brien et al., 2005), carcass and beef trimmings (Carney et al., 2006) and beef burgers and minced beef at retail (Cagney et al., 2004). Data shown in Table 3 include results for bovine hide, used as starting input data set for the model. The additional data shown were collected to validate the results of the risk model outputs.

Table 3: Prevalence and numbers of *E. coli* O157:H7 at various sample points along the beef chain in Ireland.

Sample type	Sample numbers	Number positive (%)	Numbers present (Log$_{10}$ CFU)	Reference
Bovine Hide	1500	109 (7.3)	0.13-4.24 /100 cm^2	O'Brien *et al*, 2005
Beef carcasses	132	4 (3.0)	0.70-1.41 /g	Carney *et al*, 2006
Head Meat	100	3 (3.0)	0.70-1.00 /g	O'Brien *et al*, 2005
Beef Trimmings	1351	32 (2.4)	0.70 −1.61 /g	O'Brien *et al*, 2005
Retail minced beef /burgers	1533	43 (2.8)	0.52 −4.03 /g	Cagney *et al*, 2006

Data for the retail/ domestic part of the model was based on two main sources. Information on typical consumer handling practices in the domestic environment was derived from a questionnaire survey of consumers conducted by the Market Research Bureau of Ireland (MRBI) (Mahon, Cowen and Henchion, 2003). Data on storage temperatures at retail and in domestic refrigerators was gathered from temperature studies in both environments (Kennedy et al., 2005, Duffy et al., 2005). Consumption data figures for minced beef was derived from an Irish Food Consumption Survey carried out by the Irish Universities Nutrition Alliance (www.iuna.net) (Mahon, Cowen and Henchion, 2003)

Key assumptions:
- The assumption is that the beef trimmings are boxed into 27 kg lots and trimmings from these boxes are minced into 100g beef burger patties.
- The potential growth for *E. coli* O157:H7 in the beef burger (at retail, transport to home, and in domestic environment) was adapted from the model employed in the USDA-FSIS risk assessment model using Irish data on storage times and temperatures at retail, transport and domestic stages. The calculation for the probability temperature abuse was carried out in a different manner to the USDA-FSIS model.
- The product is a 100g fresh beef burger sold in either a supermarket or a butcher shop.

- A temperature distribution was set for the cooking temperature based on the assumption that beef burgers are cooked at a temperature between 68.3ºC (well done) and rare (54.4ºC) (Normal Distribution: standard deviation ±2ºC). The log reduction as a result of cooking was then estimated. Based on a population survey, 87% of consumers prepare hamburgers well done, 12% medium and 1% cooked them rare.
- The dose response used was chosen from the literature based on USA data (Powell et al., 2000). In this EPEC was chosen to represent the lower bound of an *E. coli* 0157:H7 dose-response function as has been done in previous studies and *S. dysenteriae* was selected as an upper bound to the *E. coli* 0157:H7 dose-response function. The dose-response analysis was performed using a beta-Poisson function.

Risk estimate: Transposing the exposure assessment data through a dose-response model yielded an estimate of the probability of illness caused by exposure to *E. coli* O157:H7 in beef burgers. The probability reported is for an "average" individual. It is acknowledged that this dose-response relationship may be an underestimate for immune compromised individuals, however to try to create one for individual risk groups was not possible given the lack of reliable data for a dose-response relationship in these categories. The simulated probability of illness from a contaminated serving of fresh beef was –5.94 log (i.e. $10^{-5.94}$ = approximately 1 chance in a million).

Key findings: The sensitivity of model inputs to model predictions was modelled by rank order correlation sensitivity analysis. The initial count on bovine hides and the initial hide prevalence were significant parameters indicating the importance of minimising contaminated hides entering the slaughter plant. Cross contamination at hide removal was also a significant parameter, indicating where producers might focus efforts to reduce risk. Consumer behaviour in terms of cooking temperature and temperature abuse during transport and storage also plays an important part in dictating the final risk value, indicating the important role consumers have to play in ensuring their food is safe for consumption.

3.6   Summary

Each of the available risk assessments indicate the limitations of data and understanding in modelling the events that result in contamination of ground beef with *E. coli* O157:H7. Empirical survey data and in-depth investigation following episodes of illnesses associated with product, substantiate MRA predictions that the pathogen occurs in ground beef a low levels and low prevalence most of the time, with sporadic occurrences of high levels leading to a contaminated lot (See following section). The risk assessments all identified important factors correlated with risk, from pre-harvest to consumer, some of which may be potential targets for risk mitigation/intervention, or are highly uncertain and require further research. However, beyond application of good hygienic practices, adoption of multiple interventions at slaughter, and strict temperature controls throughout the food chain, there are no practical risk management options available today that would entirely eliminate the pathogen from live animals, from carcasses, or in raw ground product, with the exception of irradiation. Irradiation can effectively reduce the number of pathogens and result in a microbiologically safe product that retains its raw appearance.

3.7   Microbiological testing as a control measure – the pros and cons

In 1994 the USDA-FSIS declared that the presence of *E. coli* O157:H7 in ground beef is an adulterant according to USDA regulations and ground beef that tests positive must be removed from commerce. This led to a series of policy changes and the establishment of a performance standard for *E. coli* O157:H7 in ground beef based on the prevailing sampling plan and analytical procedure when the sample was collected. FSIS also 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., encourage industry to institute and maintain effective control measures)
- encourage industry to routinely sample and test raw ground beef
- find and remove from commerce product containing *E. coli* O157:H7
- expand the agency's information base and understanding in the control of *E. coli* O157:H7 (USDA-FSIS, 1994a).

Results of the sampling and testing program are summarized in Table 4. The methods of sampling and analysis have been modified since 1995 to increase sensitivity of detection. During 1995-97 a single 25g sample was analyzed. Since the beginning of fiscal year 1998, five 65g samples have been analyzed and in 2000 the analytical method was improved to increase the sensitivity by approximately 4-fold.
.
During the 1990s, the 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 USDA-FSIS it is difficult to assess the effectiveness of changes implemented by industry during slaughtering, chilling and cutting. The decrease in prevalence of *E. coli* O157:H7 in ground beef may be more apparent than real and reflect changes in industry practices for sampling trimmings and ground beef and diverting positive lots to commercial cooking operations. FSIS only samples lots that establishments have released for distribution by the producer. Since mid-2002, the majority of beef trimmings intended for the production of ground beef has been pre-tested by industry before release.

Table 4: Results from the USDA-FSIS sampling program for the period 1995 – 2005 (USDA-FSIS, 2005).

Calendar Year	No. Samples	No. Positive	% Positive
1995*	5,407	3	0.056
1996*	5,703	4	0.07
1997*	6,065	4	0.066
1998**	8,080	14	0.17
1999**	7,785	32	0.41
2000***	6,375	55	0.86
2001***	7,010	59	0.84
2002***	7,025	55	0.78
2003***	6,584	20	0.3
2004***	8,010	14	0.17
2005***	10,413	18	0.17

*25g analytical samples; ** 325g analytical samples, ***325g samples and improved isolation method (i.e., immunomagnetic beads to concentrate cells).

3.7.1 Data from ground beef implicated in illness and lots found positive

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 North-western USA frozen ground beef patties produced on November 19 and 20, 1992 were found positive. Positive samples were found in lots 4 and 9 through 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

USDA-FSIS and CDC resulted in MPN values in the range of 1-4 cells/g with a single high value of 15/g (USDA-FSIS, 1993).

Other evidence suggesting a relatively high prevalence and concentration of *E. coli* O157:H7 in certain lots of ground beef include:
- Large numbers of cases among consumers
- Multiple outbreaks involving consumers in different locations
- 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 by the store

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 contain an unusually high prevalence and concentration. It is because of this 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 6 (ICMSF, 2002).
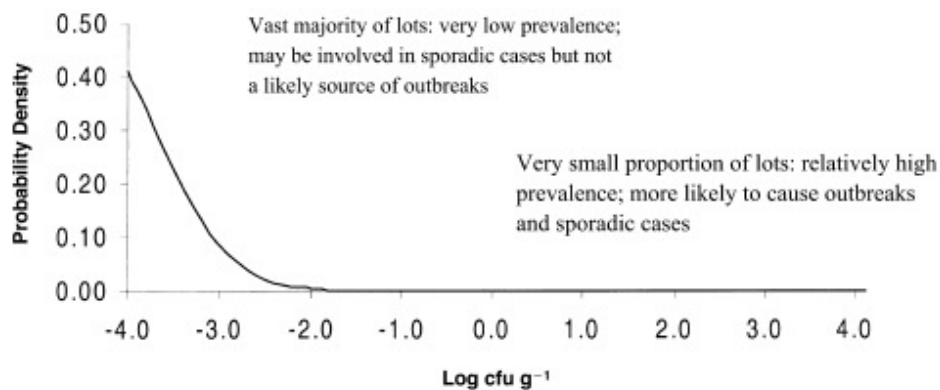

Figure 6: Illustration of the likely distribution in prevalence and concentration of *E. coli* O157:H7 in ground beef in North America.

Baseline studies on the numbers of bacteria in the USA and Canada provide further support to the general applicability of a log normal distribution for the numbers of bacteria in foods (USDA-FSIS, 1994b; CFIA, 1998). 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 7 shows an estimated log normal distribution (mean 1.2, S.D.=0.8) from counts obtained in a baseline study of the number of Biotype I *E. coli* in raw ground beef in the USA (above) compared to the hypothetical distribution for the counts of *E. coli* 0157:H7 in raw ground beef (ICMSF, 2002). In order to consider the uses and limitations of sampling for *E. coli* 0157:H7 in raw ground beef it is assumed that the counts for this organism also will have a log normal distribution and with a standard deviation value of 0.8, but a lower mean concentration. Although hypothetical, such a distribution of counts would be consistent with a prevalence of 1% positive in 325g samples taken.
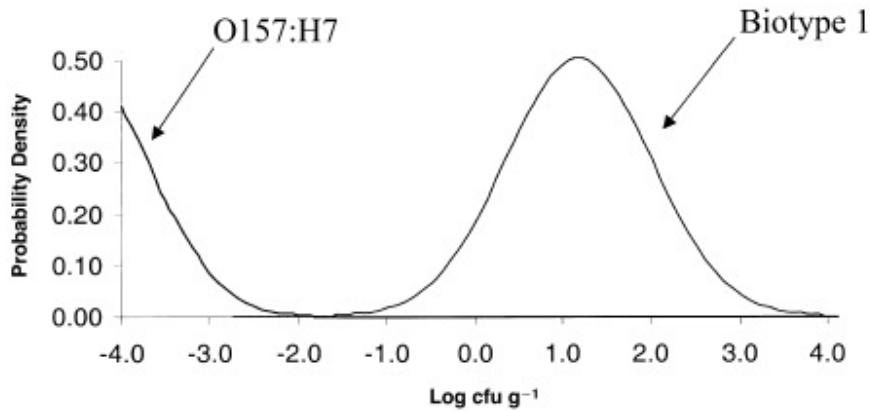
Figure 7: Comparison of hypothetical distribution in prevalence and concentration of *E. coli* 0157:H7 to fitted distribution for *E. coli* Biotype 1 (mean = 1.2, sigma = 0.8) taken from USA Nationwide Raw Beef Microbiological Survey Aug 1993 – Mar 1994 (USDA-FSIS, 1994c).

While the foregoing illustrates the hypothetical situation, prevalence survey data collected in Ireland (Figure 8) will be used in the case study to develop performance objectives.
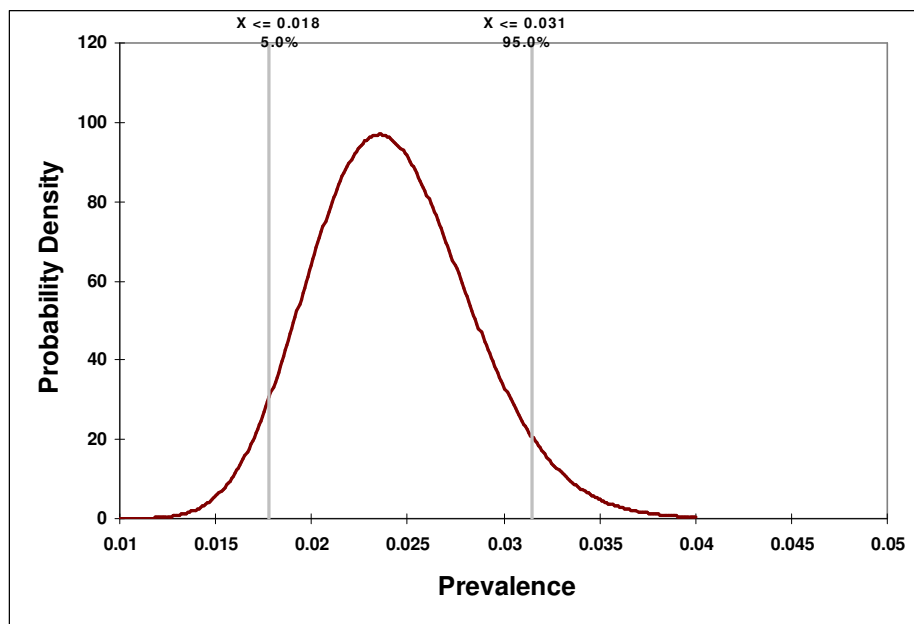
Figure 8: Distribution of *E. coli* O157:H7 prevalence in ground beef trimmings based on data presented in Carney et al., 2006.

3.7.2 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 USDA-FSIS sampling program suggest a background prevalence of less than 1% in lots pre-tested and released by industry and when analyzing 325g. 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 that which may be normally achievable from slaughter to the manufacture of ground beef with existing technology. These lots have such a low prevalence of contamination they can not be detected with any degree of confidence through routine microbiological testing. Possibly, these lots may be involved in sporadic cases, but seldom in outbreaks.

Considering the low prevalence, it is questionable that the USDA-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. However, this has resulted in the implementation of improved control measures in slaughtering operations and, since mid-2002, increased testing of beef trimmings intended for the manufacture of ground beef.

It would be impractical to implement a routine sampling plan to detect and reject contaminated lots with a ≤ 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 5.

Table 5: Probability of accepting a defective lot with indicated proportion of defective sample units.

	Number 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

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 is very ineffective for detecting lots with low prevalence of contamination.

3.7.3 Lots with unusually high prevalence

Experience indicates that a very small number of lots or portions within a lot of ground beef have a relatively high prevalence (e.g., 5% or higher) and, presumably, higher concentration of cells (e.g., 10^{-1} to about 10^1/g). In these lots it has been possible to find additional positive samples when re-sampled. 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 from trimmings from one or a few carcasses that have become contaminated during the slaughtering process and are introduced into the grinding process with other trimmings and cause a "comet-like" effect. Intensive investigation of a positive commercial lot demonstrates this effect (Figure 9, Pruett et al., 2002).
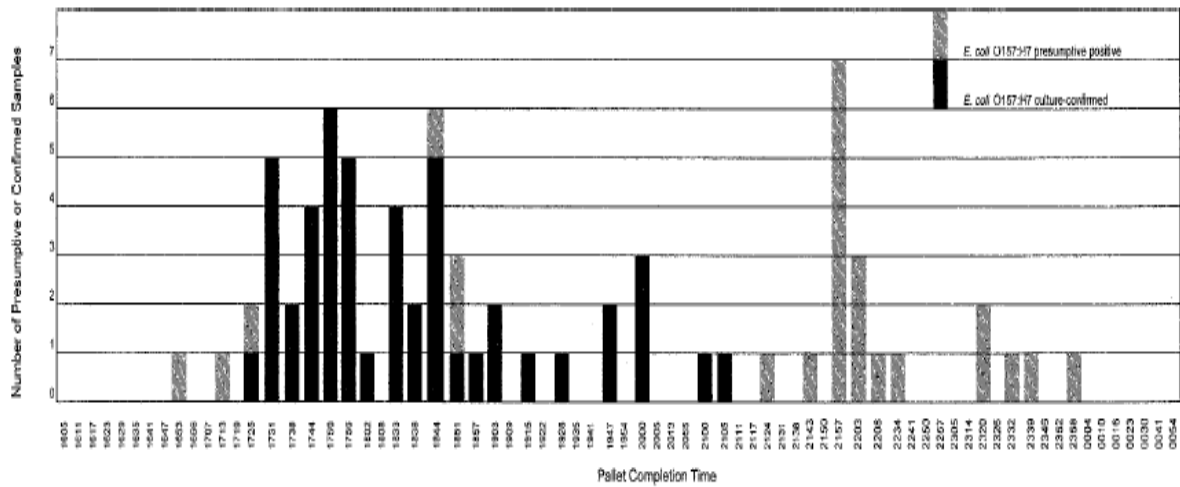
Figure 9: Distribution of presumptive (grey bars) and culture confirmed (black bars) *E. coli* O157:H7 samples from 71 consecutive pallets from a commercial lot.

It is probable that these lots or the portions of lots with an unusually high prevalence would more likely cause outbreaks as well as sporadic cases, if the ground beef is undercooked or other foods become 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 market. 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 (i.e., establish a performance objective).

4 APPLICATION OF MRA TO DEVELOP RISK MANAGEMENT STRATEGIES

4.1 Level of consumer protection And establishing Food Safety Objectives

No country to date has established an explicit Appropriate Level of Protection (ALOP) for *E. coli* O157:H7 in ground beef products based on a measure of risk.

Establishing an FSO is particularly difficult for raw foods that cannot be rendered pathogen-free, are intended to be stored and cooked by the consumer before eating, and if there is opportunity for pathogen growth under typical handling conditions. From the time the product leaves the point of manufacture, stochastic risk assessments attempt to estimate impacts of temperature abuse, undercooking, frequency of eating and amounts eaten per meal, variability in the susceptibility of the consuming population and other relevant factors. In addition, opportunity exists for cross-contamination to ready-to-eat foods in the home (none of the *E. coli* O157:H7 MRAs reviewed addressed this issue). Each of these factors is highly variable and/or uncertain, and while risk assessments may attempt to describe typical behaviours and events, the final status of the foodstuff that is consumed is beyond the control of the manufacturer and, as an FSO is defined, its application for home-prepared ground beef becomes meaningless. However, targets can still be established for processors in the form of a PO that can be linked to a level of protection for a population through a risk assessment.

4.2 Establishing a Performance Objective

Risk assessment uses outputs from the processor to estimate the risk to the population. The outputs are mathematically manipulated to reflect changes that occur post-processing as a result of various 'events' such as growth, die-off, etc., to estimate the consumer exposure in terms of frequency and dose. To better capture the true nature of the system being modelled, the uncertainty and variability associated with the system are modelled using probability distributions. The distributions account for the frequency with which various events occur and the magnitude of those events when they do occur. The end result is a distribution of risk, a function of the range of values and the likelihood of those values occurring between the processor and consumer.

Because of the lack of independence in the distributions producing the risk estimate, it is not possible to select a desirable level of risk (i.e. ALOP) and/or an FSO at the point of consumption and then 'back-calculate' to a corresponding target (i.e., PO or other criteria) at the processor level (Havelaar, Nauta and Jansen, 2004).

In order to establish criteria based on the outputs from the probabilistic risk assessment, two options may be considered. One, 'de-construct' the probabilistic model to identify factors driving specific high-risk situations, or the most important determinants for 'average' risk, and select single values along the pathway(s) of interest to develop deterministic default scenarios. This allows calculation of single values for the risk, and can be used to identify single values of the desired FSO and hence POs and so on. An alternative is to consider scenario analyses within the risk assessment by substituting plausible values at the earlier stages, and re-simulating the model to arrive at 'revised' risk estimates. The discussion of what is an acceptable level of protection can then be taken in the context of the feasibility of achieving the control needed. This is the approach taken here.

4.3   Case study

In this example, the approach was to select a range of different combinations of plausible prevalence and concentration values as hypothetical POs at the point of boxed trim (27 kg) or for formed 100 g beef patties. These values were substituted into the Irish risk model for a fresh refrigerated beef burger, and, keeping all other post-production assumptions (for storage, handling, preparation, etc.) the same as in the 'baseline' assessment, the model was re-simulated to generate corresponding outcomes for concentration (dose) and prevalence at time of consumption (after cooking), and the expected risk of illness.

Potential POs were based on data available for prevalence and numbers of *E. coli* O157:H7 in fresh ground beef. The outcome for cooked product is driven by the assumptions and data on handling, cooking and consumption; the resulting risk estimation is driven by the predicted dose, frequency of exposure, and the assumptions of the dose-response model. In this example, it is noted that the risk model does not account for specific consumer groups that may be at higher risk, such as children under the age of five.

A wide range of performance objectives were set at beef trimming stage (n=12) and for beef burgers after formation (n= 8) as outlined below.

1. Performance Objectives set for beef trimmings
PO1: Prevalence = 0.25%, counts = 1 CFU/g
PO2: Prevalence = 0.5%, counts = 1 CFU/g
PO3: Prevalence = 0.5%, counts = 100 CFU/g
PO4: Prevalence = 2%, counts = 1 CFU/g
PO5: Prevalence = 2%, counts = 100 CFU/g
PO6: Prevalence = 3%, counts = 100 CFU/g
PO13. Prevalence = 0.25%, counts = 1 CFU/100 g
PO14. Prevalence = 0.1%, counts = 1 CFU/g
PO15. Prevalence = 0.1%, counts = 1 CFU/100 g
PO16. Prevalence = 0.05%, counts = 1 CFU/g
PO17. Prevalence = 0.05%, counts = 1 CFU/100 g
PO18. Prevalence = 0.25%, counts = 1 CFU/1000 g

2. Performance Objectives set for beef burgers
PO7: Prevalence = 0.25%, counts = 1 CFU/g
PO8: Prevalence = 0.5%, counts = 1 CFU/g
PO9: Prevalence = 1%, counts = 100 CFU/g
PO10: Prevalence = 2%, counts = 100 CFU/g
PO11: Prevalence = 3%, counts = 1000 CFU/g
PO12: Prevalence = 3%, counts = 10000 CFU/g
PO19. Prevalence = 0.1%, counts = 1 CFU/g
PO20. Prevalence = 0.1%, counts = 1 CFU/100 g

The values for the Performance Objectives were run though the risk model and the predicted concentration (dose) and prevalence, probability of illness per serving and per million servings   are shown in Tables 6 and 7.

Table 6: Performance objectives set for prevalence and concentration of *E. coli* O157:H7 in raw beef trimming, prior to grinding[7].

PO Ref. #	# 6	#5	#4	#3	#2	#1	#13	#18	#14	#15	#16	#17
Prev (27kg lots)	3%	2%	2%	0.5%	0.5%	0.25%	0.25%	0.25%	0.1%	0.1%	0.05%	0.05%
CFU/g Trim	100	100	1	100	1	1	0.01	0.001	1	0.01	1	0.01
AFTER Forming & COOKING Patties Concentration (CFU/100g)												
Mean	3.07	3.07	2.25	2.94	3.09	3.27	0.19	0.24	3.13	0.24	1.69	0.09
Standard deviation	2.34	2.21	1.62	2.20	2.01	1.81	0.04	0.04	1.86	0.18	0.98	0.06
5th percentile	0.16	0.19	0.35	0.19	0.16	0.29	0.16	0.21	0.33	0.09	0.08	0.04
95th percentile	7.36	7.01	5.23	7.21	6.00	5.82	0.21	0.27	6.27	0.46	3.18	0.15
Prevalence												
Mean	3.60-04	2.44-04	2.42-04	6.19-05	6.09-05	3.08-05	7.85-06	9.46-07	1.24-05	3.21-06	6.19-06	1.56-06
Standard deviation	5.20-05	3.73-05	3.54-05	9.86-06	9.75-06	4.91-06	3.15-06	4.19-07	1.94-06	1.26-06	9.9-07	6.02-07
5th percentile	3.23-04	2.18-04	2.18-04	5.52-05	5.52-05	2.77-05	1.84-06	1.56-07	1.11-05	7.35-07	5.55-06	4.72-07
95th percentile	4.24-04	2.87-04	2.87-04	7.34-05	7.34-05	3.69-05	1.27-05	1.57-06	1.48-05	5.17-06	7.39-06	2.43-06
Log Probability of illness												
Mean	-3.07	-3.20	-3.71	-3.90	-3.68	-3.77	-7.35	-7.69	-4.33	-7.29	-5.71	-8.33
Standard deviation	1.57	1.52	1.32	1.50	1.55	1.40	0.64	0.18	1.36	0.18	0.97	0.55
5th percentile	-5.44	-5.59	-5.42	-6.18	-6.21	-6.38	-7.80	-7.82	-6.77	-7.42	-7.34	-9.12
95th percentile	-1.10	-1.29	-1.49	-1.89	-1.96	-2.28	-6.99	-7.58	-2.61	-7.06	-4.29	-7.89
Expected # illness per 1 million servings	850	630	195	125	210	170	0.04	0.02	45	0.05	2	0.005

[7] The estimates of expected cases of illness per 1 million servings were based on using single point estimates of the performance objectives in the risk model. Consequently the results should only be considered as illustrative of the process of setting performance objectives.

Table 7: Performance Objectives for raw formed beef patties[8]

PO Ref #	#12	#11	#10	#9	#8	#7	#19	#20
Prev (100g patty)	3%	3%	2%	1%	0.5%	0.25%	0.1%	0.1%
CFU/g	10000	1000	100	100	1	1	1	0.01
AFTER COOKING Concentration (Cfu/100g)								
Mean	2.37	2.94	3.01	3.05	2.59	2.80	2.70	2.02
Standard deviation	2.68	2.59	2.32	2.38	1.88	2.03	1.98	1.39
5th percentile	0.10	0.10	0.15	0.15	0.22	0.19	0.20	0.14
95th percentile	8.26	7.88	7.26	7.22	6.12	6.55	6.39	4.69
Prevalence								
Mean	3.21-06	3.22-06	2.15⁻06	1.08-06	5.35-07	2.68-07	3.21-06	3.22-06
Standard deviation	3.74-07	3.78-07	2.49-07	1.2-07	6.23-08	3.13-08	3.74-07	3.78-07
5th percentile	2.44-06	2.43-06	1.62-06	7.88-07	4.03-07	2.03-07	2.44-06	2.43-06
95th percentile	3.31-06	3.32-06	2.21-06	1.12-06	5.52-07	2.76-07	3.31-06	3.32-06
Log Probability of Illness								
Mean	-5.84	-5.34	-5.34	-5.63	-6.13	-6.30	-6.77	-7.21
Standard deviation	1.61	1.67	1.57	1.61	1.42	1.47	1.47	1.22
5th percentile	-7.56	-7.56	-7.67	-7.99	-8.22	-8.54	-8.93	-8.99
95th percentile	-3.10	-3.11	-3.32	-3.62	-4.01	-4.26	-4.68	-5.06
Expected # illnesses per 1 million servings	1.4	4.6	4.6	2.3	0.7	0.5	0.2	0.06

[8] The estimates of expected cases of illness per 1 million servings were based on using single point estimates of the performance objectives in the risk model. Consequently the results should only be considered as illustrative of the process of setting performance objectives.

4.3.1   Observations

The results of re-simulating the risk model using alternative inputs at the level of beef trimmings or formed beef patties show that risk outcomes are influenced by both prevalence and concentration. For example, in the case of beef trimmings, with a lot prevalence of 0.25% (PO Ref. #s 1, 13, 18) but with different mean concentrations (1, 0.01 or 0.001 CFU per g), the resulting (mean) risk estimates for probability of illness are 170 per 1 million servings, 4 per 100 million servings, and 2 per 100 million servings, respectively. Similarly, for the same average concentration, e.g., 0.01 CFU/g (PO Ref. #s 13, 15, 17) but at different prevalence's of contamination (0.25%, 0.1%, and 0.05%) the resulting risk values are 4 illnesses per 100 million servings, 5 per 100 million, and 5 illnesses per 1 billion servings, respectively.

In this case study, if one in a million risk is considered tolerable for a per serving exposure, then the PO choices could be #s 7, 8, 19, 20 (for raw formed patties); #s 13, 15, 17, 18 (for raw trim). Performance Objectives # 16 and 12 may be tolerable depending on the confidence in the data and whether the estimates are derived from the mean or 95th percentile. It would appear that the PO could be "no greater than 1 CFU/100g for beef trim" or "no greater than 1 CFU/g for ground beef patties before cooking". The POs need not be more stringent; likewise, POs less stringent would not provide a tolerable level of protection. Consideration also must be given to other sources of *E. coli* O157:H7 that result in disease plus whether the goal is to reduce over time or eliminate the number of cases from ground beef.

4.4   Control Measures

This section provides an example of integration of strategies for the manufacture of ground beef, as applied in the United States, which includes microbial testing. Since 1994, when *E. coli* O157:H7 was declared an adulterant in raw beef products destined to be consumed in the form of ground beef, the USDA-FSIS has tested raw ground beef for this pathogen. Some of the risk mitigation steps taken by the government since 2003 include:

- Focusing on achieving national food safety goals for reducing human illnesses associated with *E. coli* O157:H7;

- requiring industry to reassess their HACCP plans to address new information about *E. coli* O157:H7 on live animals coming to slaughter;

- accepting "negative" industry testing results when testing schemes are robust and tied to validated intervention strategies;

- expanding the list of components subject to more thorough government inspection;

- and targeting in-depth assessments of the food safety systems at suppliers who provide manufacturing trim to grinding operations.

Some of the effective risk mitigation steps taken by industry since 2003 include:

- Stopping the practice of carrying over product from one production day to the next;

- assessing the counts of microorganisms indicative of good sanitary dressing procedures and reacting to high and abnormal counts;

- using antimicrobial treatments validated to reduce counts of microorganisms;

- and implementing robust microbiological testing schemes designed to detect, with high statistical confidence, low level contamination with *E. coli* O157:H7. The following provides more detail regarding each of these important risk mitigation strategies.

4.4.1 Government activities

Partnerships: Since 1996, a partnership between the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, USDA-FSIS, and selected State and local health departments, established FoodNet in order to produce national estimates of foodborne illness. Over time, sufficient information was amassed in order to establish an estimate of the projected number of cases per 100,000 people associated with both beef and *E. coli* O157:H7. With the baseline year being 1997, the US government set a target for the year 2010 whereby the number of infections associated with *E. coli* O157:H7 should be halved from 2.1 cases per 100,000 people to 1.0 case per 100,000 people (US- HSS, 2000). The establishment of this national food safety goal provided a necessary framework for government, industry, and researchers to work within in order to gauge progress and the effectiveness of control measures.

Reassessment of HACCP Plans: With improved testing, it was recognized in 2002 that the prevalence of *E. coli* O157:H7 in faeces of live cattle coming to slaughter was higher than previously estimated (USDA-FSIS, 2005). Consequently, every establishment that manufactured beef were required to reassess its Hazard Analysis and Control Point (HACCP) plan to ensure that their food safety system remained effective. Any manufacturing trim intended for use in the production of ground beef that was found to contain *E. coli* O157:H7 would also be considered adulterated. USDA-FSIS then conducted in-depth assessments of the validation and verification support documentation that underpinned each food safety system to ensure that this pathogen was being appropriately addressed and controlled. Establishments that had incomplete or ineffective controls were required to immediately modify their HACCP plans.

Accepting "Negative" Industry Testing Results: An important factor in encouraging industry to conduct testing for *E. coli* O157:H7 was acknowledgement by USDA-FSIS that, under certain circumstances, negative testing results could be used to discern acceptable product from unacceptable product. When the pathogen was found in a test sample, only product pre-determined to be represented by the sample was deemed unacceptable. This acknowledgement by government provided industry an incentive to conduct numerous tests daily for the pathogen, with the goal of trying to find it, and not be penalized for finding the pathogen. However, in order to have sufficient confidence that such testing programs were meaningfully effective in protecting public health, and not simply a finished product sorting procedure, a number of important factors were incorporated into the food safety system (e.g., HACCP), as follows:

- Cattle slaughter and dressing procedures must be sufficiently controlled, with their effectiveness measured and documented, in order to ensure that contamination events involving faecal and digestive tract content are minimized;
- Intervention strategies, including antimicrobial treatments, needed to be applied and validated in a manner to ensure their effectiveness in reducing the incidence and counts of enteric pathogens and/or indicator organisms;
- Proper chilling of the carcasses must be attained and documented in order to ensure that any surviving enteric pathogens would not multiply;
- Manufacturing trim derived from the carcasses is tested prior to grinding in an effort to find "point source" contamination events and to segregate affected product from being used in raw

ground beef. "Point source" refers to the expectation that when faecal and digestive tract content contamination events occur whereby *E. coli* O157:H7 may be transferred to defined points on the carcass, the contaminant remains relatively confined to the point of attachment to the carcass. When the carcass is further broken down into manufacturing trim, the contaminant remains relatively confined to the area of attachment on the contaminated piece of manufacturing trim and on any adjacent pieces of manufacturing trim within the unit. Thus, if sufficient testing is conducted on one or more combo bins, there could be reasonable assurance that any grouping of combo bins was relatively "independent" of another grouping of combo bins regarding contamination with *E. coli* O157:H7;

- After grinding the manufacturing trim, the ground beef must be sufficiently sampled and tested in an effort to further find point source contamination events that may have occurred over time upon combining multiple groupings of combo bins; and

- Upon finding a positive sample through testing, producers of both the affected manufacturing trim and of the ground beef must conduct an assessment of the production process to ascertain whether all the controls are properly implemented and that the conditions involved in the production of manufacturing trim and ground beef had not sufficiently changed to warrant modifications to the food safety system.

Expanding the List of Components Subject to More Thorough Government Inspection: Initial intervention strategies for the control of *E. coli* O157:H7 focused on the application of antimicrobial treatments applied to pre-chilled carcasses. Little attention was afforded to the post-chilled carcass or to the products derived from the carcass which were intended as components in the formulation of ground beef. More recently, post-chilled carcasses and primal cuts of beef (e.g., whole sides, fore- and hind-quarters, chucks, loins, round, and plates) were incorporated into further intervention strategies whereby antimicrobials were applied just prior to boning the product into boneless manufacturing trim. By applying antimicrobials post-chilling of the carcass, the likelihood of *E. coli* O157:H7 being present was further reduced.

Pre-chilled meat from the head and the oesophagus, removed before applications of carcass interventions, are now inspected for evidence of contamination, and industry has begun to apply antimicrobial treatments to the head, cheek, and weasand meat, and testing this material for the presence of *E. coli* O157:H7.

Targeting In-depth Assessments of Food Safety Systems: In 2003, USDA-FSIS also began maintaining a list of suppliers of manufacturing trim who were identified as having supplied source materials to grinding operations in which the ground beef was found to contain *E. coli* O157:H7. All suppliers on the list were scheduled for an in-depth review of their food safety systems by specially trained government employees that focused on the design and execution of the HACCP plan, and were required to rectify any deficiencies identified.

4.4.2   Industry mitigations

Stopping the Practice of Carrying Over Product: One of the most effective early means for decreasing human exposure to *E. coli* O157:H7 pathogen was to stop the practice of carrying over ground beef from one production day to the next. By stopping this practice, industry can better distinguish one production lot from another. In addition, since the equipment used to grind and mix the ground beef traditionally is thoroughly cleaned at the end of each day, any *E. coli* O157:H7 that may have contaminated the equipment during the production day would not then be a source of cross-contamination from one production day to the next. Information regarding research specific to the role that the grinder plays in distributing *E. coli*

O157:H7 from one production lot of ground beef to the next has been published (Flores and Tamplin, 2002; Flores, 2004).

Industry is able to now apply production codes to each day's production so that if product represented by a particular code was later found to be contaminated with *E. coli* O157:H7, industry could more readily discern which day all affected product was produced and who supplied the manufacturing trim. In addition, the stopping of the practice of carrying over product from one production day to the next significantly contributed to better recordkeeping. Better record keeping associated with each production lot facilitated the trace back of product whenever product was found to be positive for the pathogen, or human illness was associated with product bearing a particular production code on product labelling.

Assessing Counts of Microorganisms Indicative of Good Sanitary Dressing Procedures: Some slaughter operations have begun testing the hides and pre-eviscerated carcasses of cattle in order to benchmark whether and how the sanitary dressing procedures and antimicrobial interventions are effective in reducing bacterial contamination. Measuring the counts (log level of colony forming units per square centimetre – log CFU/100cm^2) of indicator organisms that are reflective of effective process control (e.g., aerobic plate count – APC, and *Enterobacteriaceae)* has been instrumental in predicting whether manufacturing trim on any given day is more likely than not to be contaminated with *E. coli* O157:H7 (AMSA, 1999). Research has demonstrated that carcasses of cattle whose hides have high counts of indicator organisms are more likely to become cross-contaminated during the slaughter dressing procedures and have high numbers of bacteria, as well as have a higher likelihood of being contaminated with *E. coli* O157:H7 (Arthur et al., 2004). For example, if the level of APC or *Enterobacteriaceae* exceed 4 log CFU/100 cm^2 or 2 log CFU/100 cm^2 on hides, respectively, the likelihood of finding *E. coli* O157:H7 on pre-eviscerated carcasses is significantly higher ($P < 0.05$) than on carcasses with lower counts on hides.

Slaughter operations conducting this type of testing are able to track, from one day to the next, whether cattle are more heavily contaminated and whether their sanitary dressing procedures are capable of consistently reducing contamination on carcasses. Such slaughter operations are then able to make informed decisions about whether to apply additional antimicrobial interventions in order to better ensure that the resulting manufacturing trim is less likely to be contaminated with *E. coli* O157:H7. Such operations may also conduct more rigorous testing of the subsequently produced manufacturing trim and ground beef on days in which the hide or pre-evisceration counts were outside of the expected range.

Since testing results for indicator organisms generally are available with 24-48 hours after slaughter, the results are known in time for the carcasses to complete chilling and become staged for boning into manufacturing trim. If there is a need to treat chilled primal cuts with an antimicrobial prior to boning due to evidence that the carcasses from which the primal cuts were derived had higher than expected counts of indicator organisms, the additional treatment can be accomplished and provide an extra level of public health protection.

Validated Antimicrobial Treatments: Since *E. coli* O157:H7 was declared an adulterant in beef products, research has been targeted at developing effective intervention strategies. Many of these intervention strategies include the use of antimicrobial treatments that can be applied at multiple stages of pre- and post-harvest production. Interventions also include options that can be practically used by small volume slaughter and grinding operations (USDA-FSIS, 2002a, 2002b, 2002c).

Microbiological Testing Schemes: Because contamination by *E. coli* O157:H7 is expected to be a contaminant of the product surface as a consequence of poor sanitary dressing procedures, sample

collection methodology for pathogen testing becomes extremely important. In addition, it is important to determine whether manufacturing trim, ground beef, or both will be sampled because the sample collection process differs somewhat for each.

When sampling manufacturing trim, it is most prudent to collect samples of surface trim (i.e., an excision sample) without diluting the sample with the "sterile" layer of tissue immediately below the outermost surface (i.e., a core sample). An excision sample is collected by cutting a thin strip of muscle tissue from a portion of manufacturing trim resulting in a strip of tissue no thicker than ¼ to ½ inch and preferable from the surface portion most likely exposed during the slaughter operation. Multiple excision samples are collected from throughout the sampled unit to obtain the desired sample weight. The most common sample size currently used by large volume operations in the USA involves the collection of a composite of 60 samples (12 each from 5 combo bins representing a group; 6.25 g/unit), termed "N-60" (Murphy and Seward, 2004). In contrast, a core sample is obtained using a mechanical auger-type drill that accumulates a column of tissue from the top to the bottom layer of manufacturing trim within a combo bin, collecting both surface and internal meat tissue.

In comparing the N-60 excision sampling scheme to the core sampling scheme with both resulting in a 375 g sample, the N-60 sample contains approximately 846 cm^2 of surface tissue whereas the core sample is estimated to contain approximately 108 cm^2 of surface tissue. Although it is much easier to use the core method for collecting a sample, USDA-FSIS has received anecdotal information that core sampling recovers 39-45 percent less *E. coli* O157:H7 than the N-60 method of excising surface trim.

The N-60 scheme is a modification of the Case 15 sampling methodology (ICMSF, 2002) For high production volume operations in the USA, hundreds, and in many cases thousands, of samples are collected daily. This intense level of testing affords industry with high statistical confidence level, even as high as at least 95 percent, that if a production lot is contaminated with *E. coli* O157:H7, the organism would be detected.

Grinders of manufacturing trim also test both the pre-ground manufacturing trim and the subsequently produced ground beef. The testing of ground beef varies slightly from the manufacturing trim process in that rather than testing combo bins of ground product, a sample of ground product generally is pulled every 15, 30, or 60 minutes as the ground product emerges from the grinder. The N-60 sampling scheme involving the pulling of 60 samples, also is commonly followed for ground beef, still achieving a high level of statistical confidence of finding the pathogen. Variations of the N-60 sampling scheme include compositing four samples for every one hour or two hour period. If a single composite is positive, that "sub-lot" is retained from use as raw ground beef, as well as the sub-lots before and after the positive period.

For both the manufacturing trim and ground beef sampling procedures, if there are multiple positive periods within a day or over the course of several days, the multiple positives could call into question whether the negative sub-lots are negative. More frequent, intensified sampling than customary could provide added confidence that if the pathogen was present, it would be found.

Generally, operations that conduct extensive testing for either manufacturing trim or ground beef also have a "disposition CCP" in their HACCP plan. A "disposition CCP" refers to a critical control point being established whereby manufacturing trim and ground beef are not released into commerce for use as raw ground beef until the sample result for the presence of *E. coli* O157:H7 is known. Product that is sampled and tested positive is diverted to operations that result in ready-to-eat beef products, fully destroying the pathogen.

4.4.3   Lowered *E. coli* O157:H7 Percent Positives in Ground Beef in the US

Annually, USDA-FSIS has increased the number of tests for *E. coli* O157:H7 in ground beef. In 2005, the government testing program was expanded to include the testing of manufacturing trim prior to grinding, as well as of ground beef after grinding. Consequently, with both the government and industry mitigation strategies in place, the percent positives found in the testing program has decreased substantially over the past few years, from a high of 0.84 percent in 7,010 samples in 2002 to a low of 0.17 percent in 8,009 samples in 2004. Importantly, from 1996-2004, the incidence of *E. coli* O157:H7 infections in the USA decreased by 42 percent (CDC, 2005).

5   LESSONS LEARNED

The working group quickly came to agreement on the approach to establish Performance Objectives rather than FSOs for this type of commodity. Our working group was fortunate to have a member that was part of a team recently completing a draft risk assessment, and who could provide for us additional analysis using the risk model for examining the effect of a range of prevalence and concentration values in raw materials on the final risk outcome.

6   RECOMMENDATIONS

One of the challenges of risk modelling the farm-to-fork pathway, particularly for a raw commodity with no kill-step during manufacture, is estimating the effectiveness of various interventions that may reduce the pathogen load. This task is typically left to the risk assessors, who are to elucidate this information from published documents or other sources of information. However, reported results of mitigations, such as effectiveness of carcass decontamination procedures, are not always in agreement, nor clear-cut. For risk assessment, as well as other areas of policy-making, there is a need to undertake investigations that critically evaluate published data on the basis of defined criteria pertaining to quality of the work (e.g., methodology, sampling, conditions of experimentation). Methods such as systematic reviews and meta-analysis for 'evidence synthesis' have been used in other fields, and are just beginning to be applied in agri-food and zoonotic public health. Collaborative efforts to evaluate research findings and to quantitatively describe the effects of various stages of the food chain on pathogens would provide much needed inputs for risk modellers, improve quality of microbial risk assessments, and ultimately help to inform risk management decisions.

A useful output from any microbial risk assessment, and perhaps should be part of the final documentation, is the comparison of a range of pathogen prevalence and concentration values, at one or more steps in the exposure model, and how changes in either one or both would affect the final risk estimate (for example, the P-D equivalence curve described by Havelaar, Nauta and Jansen, 2004). Results of such an analysis can lead to consideration of interventions that impact either prevalence, or concentration, or both. This also aids in consideration of to what extent the pathogen levels must be reduced to achieve desirable risk reductions.

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