TRANSACTIONS OF THE AMERICAN CLINICAL AND CLIMATOLOGICAL ASSOCIATION, VOL. 114, 2003

THE COLOR OF HAMBURGER: SLOW STEPS TOWARD THE DEVELOPMENT OF A SCIENCE-BASED FOOD SAFETY SYSTEM IN THE UNITED STATES

J. GLENN MORRIS, JR.

BALTIMORE, MARYLAND

ABSTRACT

Concerns about food safety have played a key role in the emergence of the public health system in the United States. Unfortunately, the food safety regulatory system that was established in the early part of the 20th century in response to these concerns has not kept pace with our advancing scientific knowledge. In 1995, basic changes were made in the structure of the U.S. food safety regulatory structure, including implementation by USDA of the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule for Meat and Poultry, from USDA's Food Safety and Inspection Service (FSIS); this was accompanied by creation of FoodNet, a sentinel surveillance system for active collection of foodborne disease surveillance data. The most recent FoodNet data show a 21% decline in the incidence of major bacterial foodborne diseases since implementation of the new regulations, a decrease paralleled by reductions in the frequency of contamination of meat and poultry with *Salmonella.* These data strongly support the public health importance of these regulatory changes. However, questions remain about the relative degree of responsibility of industry vs. the consumer in assuring safe food; the appropriateness of microbial standards for raw food products; and the directions that should be taken in the development of the "next generation" of food safety regulations.

BACKGROUND

The modern public health system in the United States traces its origins to the latter part of the 19th and early 20th centuries, with its development paralleling the shift of the U.S. population from rural to urban settings. Data from the mid-19th century suggested that the life expectancy of persons in urban areas was declining (1), leading to demands for government interventions to control epidemics of disease. Before the 1870s almost all of the food consumed in the United States was either made in the home or purchased from neighbors; gradually,

however, more and more food came from factories or was shipped long distances to market, so that consumers were increasingly dependent on unknown sources for much of what they ate (2,3). In response to these changes, public health authorities came to place a major emphasis on provision of safe food and water for the burgeoning urban populations.

Medical science in the late 18th and 19th centuries equated dirt with disease, and consequently these early public health regulatory efforts were generally targeted toward sanitation and elimination of "filth" (4). By the end of the 19th century there was increasing recognition that infectious diseases resulted from the action of microorganisms. However, despite the explosion in microbiologic knowledge, public health officials continued to focus much of their effort on elimination of "filth, foul odors, and the decomposition and fermentation of animal and vegetable matter" (5). It was in this social and scientific context that Upton Sinclair published *The Jungle*, a scathing commentary on the industrial society of the day that portrayed numerous abuses in the slaughter industry. Responding to this book and associated public concerns, congress in 1906 passed the Federal Meat Inspection Act, which provided for inspection of slaughter facilities, to prevent introduction of dead, diseased, disabled, and dying animals into the food supply. In keeping with the prevailing public health views, the scientific basis for this act was firmly planted in the filth theory of disease. It included no mention of specific pathogens; instead, inspectors used their sight, touch, and smell ("organoleptic" inspection) to detect and exclude filth and dead and diseased animals from slaughter.

By the early 1980's, there was an increasing consensus that these approaches had far outlived their usefulness, particularly in dealing with what were increasingly being recognized as the primary causes of meat and poultry-associated foodborne illness. Pathogens of contemporary concern included *Salmonella, Campylobacter, Yersinia, Listeria,* and *E. coli* O157:H7 (identified for the first time in 1982) (Table 1).

TABLE 1
Estimated Annual Costs Due to Selected Foodborne Pathogens, 2000

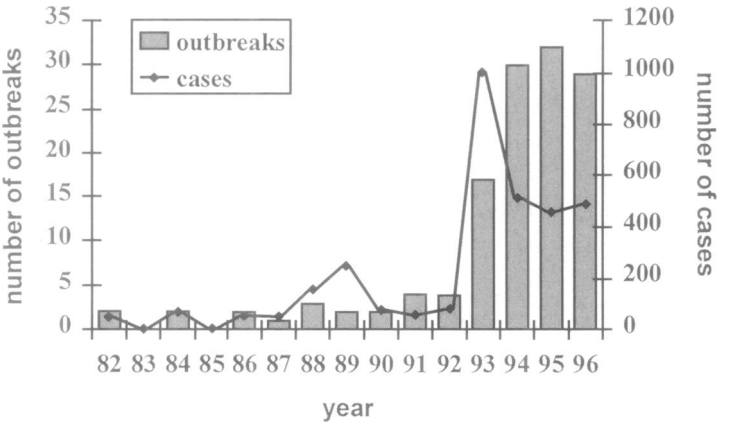
Pathogen	Cases	Hosp	Deaths	Costs (billion $)
Campylobacter	1,963,141	10,539	99	1.2
Salmonella	1,341,873	15,608	553	2.4
E. coli O157:H7	62,458	1,843	52	0.7
E. coli STEC	31,229	921	26	0.3
Listeria	2,493	2,298	499	2.3
Total	3,401,193	31,209	1,229	6.9

Data from reference 16.

Salmonella, Campylobacter, Yersinia, and *E. coli* O157:H7 are all capable of colonizing healthy animals; *Listeria* is an environmental organism that is a common colonizer in processing plant environments. As such, removal of dead, diseased, dying, or disabled animals from the food supply (the primary objectives of the 1906 regulation) has limited utility in preventing outbreaks of human disease caused by these microorganisms. Conversely, the animal diseases identified by inspectors, with rare exceptions, can not be transmitted to humans. Inspectors did focus on reduction of fecal contamination of raw product; however, inspectors were only able to deal with contamination that they could see, and there were concerns that there was a great deal more contamination that they could not see. Between 1985 and 1990, these issues were dealt with by three successive National Academy of Sciences/Institute of Medicine expert committees (6–8): all three noted the serious deficits in the current system, and recommended a shift toward a "science-based" inspection system. In the words of the 1985 committee: "the committee could find no clear evidence that the traditional inspection system and modifications to it over the years are based on objectives and criteria that relate to public health" (6).

While there was a growing scientific consensus that the existing inspection system was seriously flawed, it required an outbreak to motivate change. *E. coli* O157:H7 was an "emerging" pathogen, first identified in 1982, and linked with episodes of bloody diarrhea (and hamburger). O157:H7 strains can colonize the intestine of cattle, and, during the slaughter process, contaminate the cut surface of meat. In the mixing which occurs during the preparation of hamburger, these microorganisms can contaminate the center of the patty (9); if the hamburger is not fully cooked (and 23% of the U.S. population in 1990 did not fully cook their hamburger, preferring it rare or medium rare), they can cause illness, particularly in the very young or very old, who are at greatest risk for infection. The ability of O157:H7 strains to cause illness is enhanced by the low infectious dose of the organism: ingestion of less than 100 bacteria (and, in at least one study, as few as two bacteria [10]) is sufficient to cause an infection. Between 1982 and 1992 the number of reported O157:H7 cases and outbreaks remained relatively low (Figure 1). This changed in 1993, when a major outbreak of *E. coli* O157:H7 infections occurred in seven western states, associated with eating hamburgers from the Jack-in-the Box chain. Over 500 people ultimately were found to have culture-confirmed cases, with 41 persons developing hemolytic uremic syndrome, and 4 children dying.

This outbreak placed a renewed focus on the overall issue of food safety, and led to strong public pressure for government regulatory



*Data from Epidemiology and Emergency Response Program, FSIS, USDA

FIG. 1. Reported outbreaks/cases of *E.coli* O157:H7, 1982–96*.

reform. As the discussion widened, it also brought to the forefront the very basic question of consumer vs. industry responsibility. Traditionally, the meat and poultry industry had maintained that raw products were never intended to be free of pathogens, and that it was the responsibility of the consumer to cook and handle the product appropriately so that it did not cause illness, a viewpoint that had been backed in court decisions. However, the appearance of *E. coli* O157:H7, with its low infectious dose and ability to cause illness and death in children in association with eating a culturably acceptable food item (a medium rare hamburger)—and the increasing recognition of the overall frequency with which foodborne pathogens caused illness—led consumer groups to vigorously challenge the concept that responsibility for illness lay entirely with the consumer.

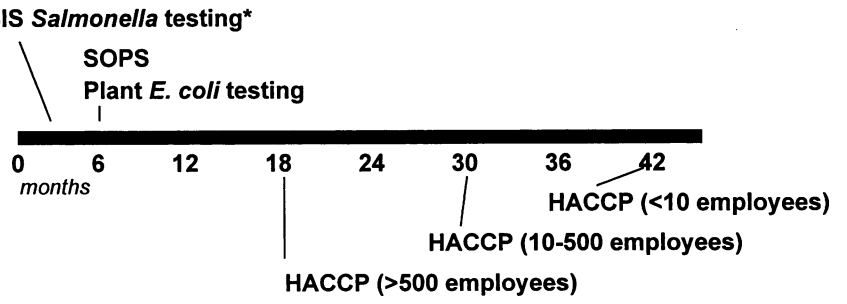
In coming to grips with the O157:H7 problem, there was initial consensus among all groups that, at a minimum, consumers should always monitor hamburger color; it was thought that if patties that were red or pink in the middle were cooked until they turned brown, O157:H7 strains would be killed, and the risk of illness would be eliminated. However, it was subsequently shown that the color of hamburger, while useful, was not an absolute marker for cooking temperature (and safety). The red color of hamburger is dictated primarily by the level of oxygenation of its myoglobin pigment, resulting in a ferrous iron-oxygen complex; cooking results in denaturation of the pigment and appearance of the typical gray/brown color of cooked hamburger. However, if meat is stored for long periods of time, is

stored above proper temperatures, or is exposed to too much air, the ferrous iron becomes ferric iron, forming met-myoglobin, which has a brown pigment. Studies have shown that up to 25% of hamburger patties may turn brown prematurely; conversely, if meat has a higher pH, less myoglobin may be denatured at a given temperature, resulting in a persistent red color after "adequate" cooking (11). These observations underscored the problems inherent in making the consumer assume sole responsibility for food safety, and the corresponding need for industry to minimize the risk that foodborne pathogens were present in raw products.

DEVELOPMENT OF A NEW REGULATORY SYSTEM

In 1994, under the leadership of Mike Taylor, USDA's Food Safety Inspection Service (FSIS) began a review and revision of existing food safety regulations for meat and poultry. This, in turn, lead to the publication of the Pathogen Reduction; Hazard Analysis and Critical Control Points Final Rule in July, 1995—the first major revision of the food safety regulatory system since 1906.

In keeping with recommendations in NAS and other expert reports, the new regulatory system was based on the Hazard Analysis—Critical Control Points (HACCP) concept. This concept, which had been used in preparing food for the space program, requires that the producer identify potential hazards in the product (i.e., *E. coli* O157:H7 in ground beef, *Campylobacter* in chicken), develop interventions to minimize or eliminate this risk, and then identify critical control points that are monitored to assure that risk is reduced. As recently summarized in a National Academy report (12), the regulations required all meat and poultry slaughter and processing establishments to design and implement a HACCP system, with the schedule of implementation dependent on plant size (Figure 2). The exact elements of the HACCP plan were not specified, to encourage companies to carefully evaluate the particular public health hazards associated with each specific product line/plant; to have the freedom to develop innovative methods for control of these hazards; and to have the flexibility to identify critical control points that would have maximal utility in control of the plant processes and achievement of food safety goals. There was also recognition that many of the major foodborne hazards/pathogens were colonizers of the animal intestinal tract, and, consequently, there was value in monitoring (and minimizing) fecal contamination of carcasses. As such, the Final Rule required that, as part of their HACCP pro-



*regulatory compliance required with HACCP implementation

FIG. 2. Pathogen reduction/HACCP implementation schedule.

gram, plants implement a microbiologic monitoring program for generic *E. coli*, as a marker for fecal contamination.

While efforts were being made to encourage flexibility and innovation though implementation of HACCP, there was also recognition that there had to be some type of regulatory "floor," to clearly define minimal acceptable levels of performance. As the goal of these regulatory changes was to reduce the incidence of meat- and poultry-associated foodborne illness, it was felt that such standards should focus on the effectiveness of a plant's HACCP program in reducing contamination of product with specific, known pathogens. At the time the Rule was being prepared, *Salmonella* species were recognized as having the greatest economic impact among the known bacterial foodborne pathogens. *Salmonella* was also present in all product classes that were being regulated; and it could be readily isolated, with well-established laboratory methodology available for its identification. Based on these considerations, the decision was made to establish a *Salmonella* performance standard. Given the ability of microorganisms to rapidly multiply once present on a carcass (and recognizing some of the technical issues involved in trying to quantitate *Salmonella* on a single carcass), the percentage of carcasses contaminated was used as the basis for the standard. The decision was made to set the initial standard at a level equal to the current national mean for that product class (i.e., in studies conducted in the early 1990's, 25% of broiler chickens nationally were found to be contaminated with *Salmonella*, and, consequently, the *Salmonella* performance standard for plants was set at 25% contamination). The concept was that the new standards would create accountability for all slaughter plants to target and control for Salmonella and require plants performing worse than the

national mean to at least bring their incidence of contamination down to that level.

SURVEILLANCE METHODOLOGY

In addition to monitoring *Salmonella* contamination of product at individual plants (and in keeping with NAS and other expert recommendations), FSIS, working with FDA and CDC, set up a national sentinel surveillance system to provide active surveillance data for foodborne disease; a major objective of this system was to provide data to assess the effectiveness of the HACCP rule in reducing the national incidence of foodborne illness. This system, which came to be named FoodNet, started with five sites (Northern California, Connecticut, Georgia, Minnesota, and Oregon), with subsequent expansion to 9 sites (addition of Maryland, New York, Colorado, and Tennessee), covering approximately 10% of the U.S. population (13); New Mexico has just been added as a tenth site. FoodNet surveillance includes active laboratory-based surveillance for *Salmonella, Shigella, Campylobacter, E. coli* O157:H7, *Listeria monocytogenes, Yersinia enterocolitica, Vibrio* species, and the parasites *Cryptosporidium* and *Cyclospora.* It also includes periodic surveys of clinical laboratories, to evaluate frequency of (and techniques for) routine screening of stool samples for specific pathogens; physician surveys, to determine the frequency with which physicians order stool cultures and other relevant laboratory tests and their approach to case management; population surveys, to determine frequency of occurrence of illness, and, in particular, to assess the relationship between frequency of illness and frequency of visits to a physicians office; and epidemiologic studies, looking at risk factors for infection with specific pathogens (13).

RESULTS

Since implementation of the new food safety regulations, FSIS has not repeated national random surveys to document the frequency of contamination of raw product with specific pathogens. However, as noted above, the regulations incorporate a program of periodic government monitoring of the frequency of *Salmonella* contamination at each plant. Data from these periodic surveys for selected product categories and plant size are summarized in Figure 3 (14). In general, trends have been downward, with clear reductions in contamination rates for certain product categories (such as broilers from large plants and ground turkey). For other categories, there has not been as clear a change (i.e., market hogs, large plants); it should also be noted that for these

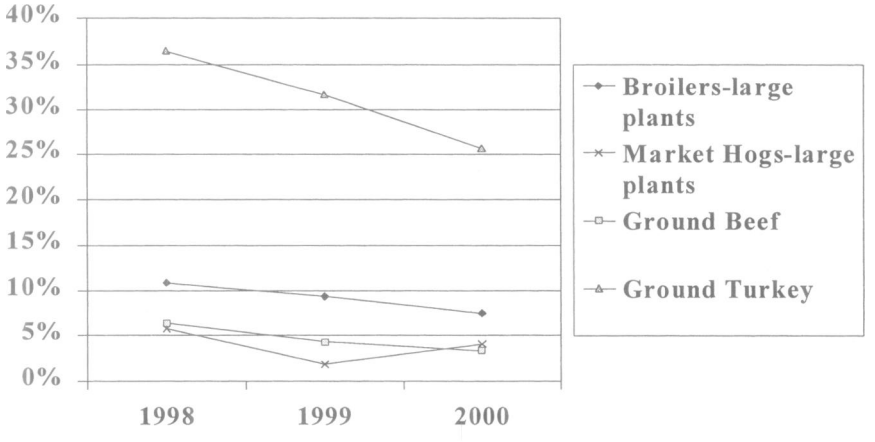


FIG. 3. Percentage of product contaminated with *Salmonella*, USDA testing, 1998–2000.

product categories, current contamination frequencies are below the 50th percentile baseline that served as the starting point for the regulation.

For major foodborne pathogens (*Salmonella, Campylobacter, Listeria,* and *E. coli* O157:H7), FoodNet data show a 21% decrease in incidence between 1996 and 2001 (13,15). As shown in Figure 4, this includes a 27% decrease in *Campylobacter*, a 35% decrease in *Listeria*,

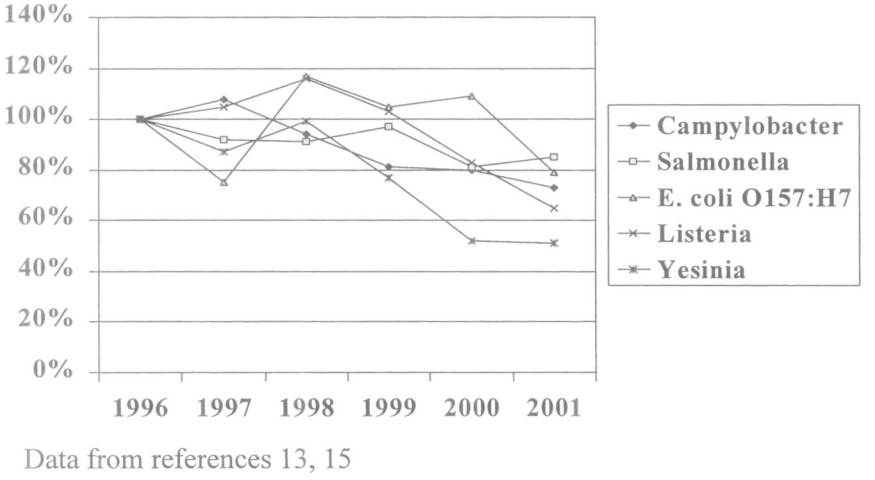


FIG. 4. Changes in incidence of selected FoodNet pathogens, 1996–2001.

and a 15% decrease in *Salmonella; Yersinia* shows a 49% decrease. While there is a decrease for *E. coli* O157:H7 in 2001, the *E. coli* numbers have shown movement above and below the baseline during the 6 year period, making it less clear that there has been a definite, sustained decrease in incidence.

DISCUSSION

Bacterial foodborne illness remains an important public health problem in the United States, as reflected in the 2000 data from the USDA's Economic Research Service showing an estimated $6.9 billion annual cost in medical expenses and lost productivity associated with *Campylobacter, Salmonella, E. coli* O157:H7 (and other Shiga toxin-producing [STEC] *E. coli*) and *Listeria* (Table 1) (16). FoodNet data suggest that, with the possible exception of *E. coli* O157:H7, incidence rates for all of these pathogens are declining. While the epidemiology of these foodborne pathogens is complex, and there could be a number of reasons for the observed decrease in incidence, it is likely that at least part of the decrease is attributable to the new food safety regulations that were phased in over this same time period. Support for this association is provided by the FSIS frequency of contamination data for *Salmonella* (14), which indicate that implementation of the new regulations had an impact on pathogen contamination of raw product.

At the same time, major challenges remain. Supreme Beef, a company that had failed the *Salmonella* performance standard three times and was in danger of being shut down, brought USDA/FSIS to court, saying that the agency's primary statutory authority (dating back to the 1906 Federal Meat Inspection Act) did not give it the right to enforce a pathogen-based microbial performance standard in raw product. A Federal Appeals Court has agreed, effectively eliminating the ability of FSIS to enforce microbial standards; movement back to where we were even a year or two ago will require enactment of new federal legislation, to bring the statutory authority for meat and poultry inspection in line with scientific advances of the past century (and away from the "filth" theory of disease). Closely linked with this is the striking fragmentation of regulatory responsibility for food in this country: at least a dozen federal agencies implement more than 35 statutes and are overseen by 28 congressional committees (17). Jurisdiction over a particular food, or a particular problem, can depend on a variety of factors, including geography, the type of product (e.g., products with >3% meat or poultry are regulated by FSIS at USDA, while those with <3% meat or poultry are regulated by FDA), and the

level of the food chain at which the problem is found. A National Academy Committee that has recently examined this issue has recommended the creation of a single food agency, as a critical step in movement toward a rational, science-based food inspection system (17).

Problems also remain relating to availability of data, and the ability of regulatory agencies to develop appropriate food safety regulations. In the absence of data clearly linking frequency of pathogen contamination of raw product with specific risks of illness, the *Salmonella* performance standards included in the new 1995 food safety regulations were "technology based"—i.e., they were based on what the industry could do (reduce frequencies of contamination below the national mean at that time), and assumed that the resulting reductions in frequency of contamination would result in a reduction in disease incidence. As noted above, this appears to have worked. However, to move forward, with a strong, science-based system, there is a need to better define microbial performance standards for raw products, and more closely link these standards with disease occurrence. Accomplishing this will require additional data on rates of illness and levels/frequency of microbial contamination on raw products, as well as the application of risk assessment and other modeling techniques currently under development.

These issues also continue to be driven, at a societal level, by very basic questions about the relative responsibility of consumers vs. industry in prevention of foodborne illness: what responsibility must be assumed by industry, and to what extent are government regulations necessary and appropriate to minimize risk associated with food? Resolution of these issues will require ongoing discussions among consumers, government regulators, and industry, as we seek to further reduce the public health impact of foodborne illness on our society.

REFERENCES

1. Hutt PB, Merrill RA. Food and Drug Law: Cases and Materials (2d ed. 1991), p. 7, citing Report of the Sanitary Commission of Massachusetts 220 (1850).
2. Alsberg CL. Progress in federal food control. In: Ravenel MP (ed). *A Half Century of Health.* American Public Health Association. New York: Arno Press & the New York Times. 1970. Pp. 211–220.
3. Roe RS. The Food and Drugs Act—past, present, and future. In: Welch H, Marti-Ibanez F. *The Impact of the Food and Drug Administration on our Society.* New York: MD Publications, Inc. 1956. Pp. 15–17.
4. Chapin CV. History of state and municipal control of disease. In: Ravenel MP (ed). *A Half Century of Health.* American Public Health Association. New York: Arno Press & the New York Times. 1970. Pp. 133–160.
5. Gorham FP. The history of bacteriology and its contribution to public health work. In: Ravenel MP (ed). *A Half Century of Health.* American Public Health Association.

New York: Arno Press & the New York Times. 1970. Pp. 66–93.
6. NRC. Meat and Poultry Inspection: The Scientific Basis of the Nation's Program. National Academy Press: Washington, D.C., 1985.
7. NRC. Poultry Inspection: The Basis for a Risk Assessment Approach. National Academy Press: Washington, D.C., 1987.
8. IOM. Cattle Inspection. National Academy Press: Washington, D.C., 1990.
9. Armstrong GL, Hollingsworth J, Morris JG Jr. Emerging foodborne pathogens: *E. coli* O157:H7 as a model of entry of a new pathogen into the food supply of the developed world. Epidemiol Rev 1996;18:29–51.
10. Tilden J Jr, Young W, McNamara A-M, Custer C, Boesel B, Lambert-Fair MA, Majkowski J, Vugia D, Werner SB, Hollingsworth J, Morris JG. *Escherichia coli* O157:H7 infection associated with consumption of dry fermented salami: New routes of transmission for an emerging pathogen. Am J Pub Health 1996;86:1142–1145.
11. FSIS. *Http://www.fsis.usda.gov/OA/pubs/colortech.htm.* Last updated May, 2000.
12. NRC. Scientific Criteria for Food Safety. National Academy Press: Washington D.C., 2003.
13. CDC. *Http://www.cdc.gov/foodnet/what_is.htm.* Last updated October, 2002.
14. Rose BE, Hill WE, Umholtz R, Ransom GM, James WO. Testing for *Salmonella* in raw meat and poultry products collected at federally inspected establishments in the United States, 1998 through 2000. J. Food Protect 2002;65:937–947.
15. CDC. Preliminary FoodNet data on the incidence of foodborne illnesses—selected sites, United States, 2001. Morbid Mortal Weekly Rep 2002;51:325–9.
16. ERS. *Http://www.ers.usda.gov/Emphases/SafeFood/features.htm.* Last updated November, 2001.
17. NRC. Ensuring Safe Food. National Academy Press: Washington, D.C., 1998.

DISCUSSION

DuPont, Houston: Glen very nice, thank you. You're heavily involved in molecular biology, and thanks for showing a little bit different approach to a public health problem. I just came from a meeting at NIH the last few days, the Blue Ribbon panel on biodefense for category B and C agents, and one of the agents that's receiving a lot of attention from NIH right now, in terms of bioterrorism is shiga-toxin producing *E. coli.* It's a low dose pathogen, it's not easily detectable, it's not easily treatable, and it has secondary spread. Thus it's got many things to get our attention. You identified one problem and that's detection, and I want you to comment about that for shiga-toxin producing *E. coli.* Many of the strains are not 0157H7, so a serotype dependent detection system may fail from the outset. How are we going to find these bugs, and how are we going to monitor shiga-toxin producing *E. coli* in the United States?

Morris, Baltimore: It's a huge problem. It's a huge problem at the regulatory level, because at the moment I will have to say we are not doing a good job in terms of preventing it in the food supply. It's a huge problem from a bioterrorism standpoint. I will shift to my molecular genetics hat and say that we are working on development of microrays that look at variety of genes that we hope will allow rapid detection of the organism and we are using some fairly sophisticated technology to be able to enhance the sensitivity of the microrays. You know, some of this is still Buck Rogers type stuff, but we are hopeful that within a year or two we will have something that will allow us to begin to get a better handle on detection. Because right now, right now it's a problem. We simply can't identify the organism sufficiently well to allow to track it and put in place regulatory controls.

Vercellotti, Minneapolis: I wonder if you could comment about radiation of meat, and why don't we just do that?

Morris: Good question. The standard answer that I learned when I was at USDA is that radiation is one component of an overall food safety system. Obviously for those of you who are not familiar with radiation, you can irradiate meat; low dose of radiation of meat has been approved. It kills off the *E. coli* 0157H7, and it is an effective methodology, comparable say to pasteurization of milk. There have been major issues in terms of consumer acceptance and costs. Profit margins in the industry are razor thin, and there is not felt to be a sales advantage to irradiation. When consumers are confronted in various focus group type settings, with a package of irradiated meat that costs a little bit more versus a package of unirradiated meat, and the law requires that if meat is irradiated it must say so on the label, the consumer will always take the unirradiated cheaper meat. And so we are not quite there yet. However, this is clearly a direction at which we need to look.