standing of ways to affect legislative issues that decrease tobacco consumption. □

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A New Route of Transmission for *Escherichia coli:* Infection from Dry Fermented Salami

John Tilden, Jr., DVM, MPH, Wallace Young, Ann-Marie McNamara, PhD, Carl Custer, MS, Barbra Boesel, MS, Mary Ann Lambert-Fair, Jesse Majkowski, MPH, Duc Vugia, MD, MPH, S. B. Werner, MD, MPH, Jill Hollingsworth, DVM, and J. Glenn Morris, Jr., MD, MPHTM

ABSTRACT

Objectives. This study evaluated the production of dry fermented salami associated with an outbreak of *Escherichia coli* O157:H7 infection in Washington State and California.

Methods. Facility inspections, review of plant monitoring data, food handler interviews, and microbiological testing of salami products were conducted.

Results. Production methods complied with federal requirements and industry-developed good manufacturing practices. No evidence suggested that postprocessing contamination occurred. Calculations suggested that the infectious dose was smaller than 50 *E. coli* O157:H7 bacteria.

Conclusions. Dry fermented salami can serve as a vehicle of transmission for O157:H7 strains. Our investigation and prior laboratory studies suggest that *E. coli* O157:H7 can survive currently accepted processing methods. (*Am J Public Health.* 1996;86:1142–1145)

Introduction

Dry fermented salami is representative of a class of traditional products in which raw, ground meat is preserved by a process of fermentation and drying.[1] The lowered pH caused by fermentation and the decreased available moisture caused by drying, when combined with the inhibitory effects of salt, curing agents, and other spices, create a hostile environment for most pathogenic bacteria.[2,3] These products are considered ready to eat and are generally not cooked before consumption.

In November 1994, an outbreak of 17 cases of *Escherichia coli* O157:H7 infection in Washington State and California was linked epidemiologically to consumption of presliced dry fermented salami (brand A).[4] *E. coli* O157:H7 had been isolated from two intact packages of brand A salami collected at the retail level, with isolates from patients and the implicated salami having identical patterns by restriction fragment-length polymorphism analysis. Salami implicated in these outbreaks had been produced by a single facility (plant S) on August 25, 1994. Hypotheses for the presence of *E. coli* O157:H7 in this ready-to-eat product included the following: (1) Organisms present on raw meat ingredients survived a substandard fermentation and drying

John Tilden, Jr., Jesse Majkowski, Jill Hollingsworth, and J. Glenn Morris, Jr., are with the Epidemiology and Emergency Response Program, Food Safety and Inspection Service, US Department of Agriculture, Washington, DC. John Tilden, Jr., is also with the Epidemiology Program Office, Centers for Disease Control and Prevention, Atlanta, Ga. J. Glenn Morris, Jr., is also with the University of Maryland School of Medicine and the Veterans Affairs Medical Center, Baltimore, Md. Wallace Young and Barbra Boesel are with Inspection Operations, Food Safety and Inspection Service, Alameda, Calif. Ann-Marie McNamara and Carl Custer are with the Science and Technology Program, Food Safety and Inspection Service, Washington, DC. Mary Ann Lambert-Fair is with the National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta. Duc Vugia and S. B. Werner are with the Division of Communicable Disease Control, California Department of Health Services, Berkeley.

Requests for reprints should be sent to J. Glenn Morris, Jr., MD, MPHTM, Epidemiology and Emergency Response Program, Food Safety and Inspection Service, US Department of Agriculture, Washington, DC 20250.

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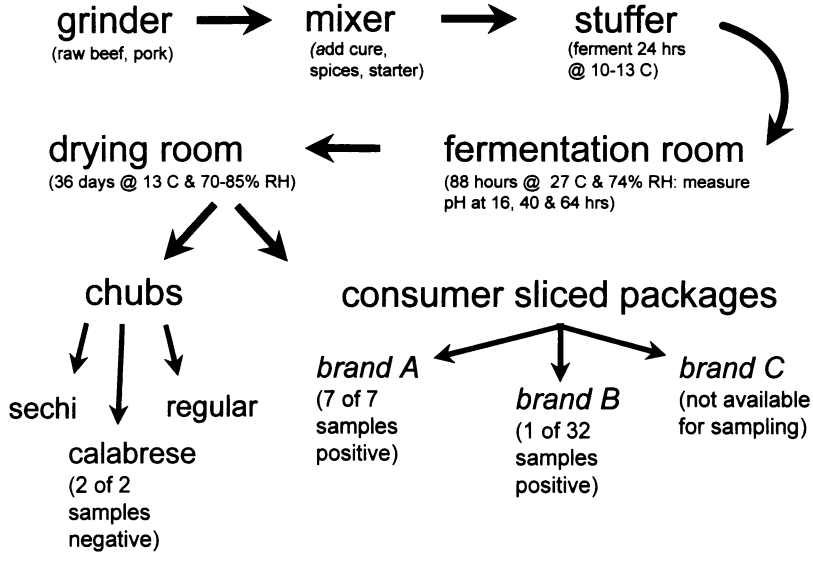
process; (2) organisms survived a fermentation and drying process that met existing industry and regulatory standards; and (3) contamination occurred after fermentation and drying, either during the slicing process or as a result of subsequent handling. We undertook an investigation to determine whether available evidence supported any of these hypotheses.

Methods

Environmental evaluations of plant S were conducted between December 5, 1994, and February 15, 1995. Plant layout, processing methods and equipment, and employee work practices were evaluated. To determine the process used to produce brand A salami, we reviewed the environmental and product monitoring data routinely collected by the plant. These data included fermentation and drying room temperature, room relative humidity, salami internal pH, and the moisture–protein ratio of finished salami. To determine routine employee work practices, we interviewed production workers who had direct contact with the brand A salami, plant managers, plant quality control specialists, and on-site United States Department of Agriculture Food Safety and Inspection Service personnel.

Investigators collected a convenience sample of salami that was produced in plant S on August 25, 1994, and that was still stored at the plant warehouse on December 3, 1994. Three-pound (1.4-kg) samples were collected from 32 intact cases and submitted to the Food Safety and Inspection Service Microbiology Laboratory in Beltsville, Md. Thirteen 25-g subsamples were taken from each sample and cultured for *E. coli* O157:H7 by using standard US Department of Agriculture/Food Safety and Inspection Service methods.[5–7] Isolates from these samples, from patients, and from epidemiologically linked salami samples collected at the retail level by state and local health departments were compared by pulsed field gel electrophoresis[8] at the Centers for Disease Control and Prevention.

The Food Safety and Inspection Service Microbiology Laboratory conducted additional testing of *E. coli* O157:H7–positive samples to determine the most probable number of *E. coli* O157:H7 present.[9] The internal pH, salt content, and moisture–protein ratio of these salami samples were also determined. Infectious dose estimates were calculated by using the highest most probable number of *E. coli* O157:H7 detected and consumption data provided by the Seattle–King County Department of Public Health (M. Davis, written communication, December 1994).



Note. RH = relative humidity.

FIGURE 1—Flow diagram of production of lot X of dry-fermented sausage, plant S, and summary culture results for various product categories.

Results

Plant S was constructed in 1967. Solid doors and floor-to-ceiling walls separated raw meat processing areas from areas where dry fermented salami was processed. Separate crews of employees worked in these areas, with no apparent sharing of equipment. Employees who worked directly with finished salami wore white jackets, aprons, and disposable gloves. Employees are provided paid sick leave to discourage their working while ill.

An outline of the procedures used in production of dry fermented salami in plant S is shown in Figure 1. Salami batter was created by mixing ingredients in 310-lb batches. The same grinding and mixing equipment, which was not sanitized between batches, was used to produce all types of salami. The salami produced in plant S on August 25, 1994 (lot X), consisted of sechi, calabrese, regular chub, and slicing salami; each was prepared with a slightly different recipe, although drying and fermentation conditions were the same.

The approximately 16 390 lb of slicing salami produced that day represented 53 batches. Ingredients incorporated in the slicing salami included commercially purchased spices and curing agents, reconstituted starter culture, and raw meat (71% pork products and 29% beef trimmings). Plant records indicated that any of six suppliers could have provided beef incorporated in the lot X salami.

After it was mixed, the salami batter was stuffed into synthetic casings and held for 24 hours at 10°C to 13°C. The salami were then fermented in an environmentally controlled room at 20°C to 27°C and 70% to 80% relative humidity. Internal pH measurements taken from lot X salami showed the following levels: 5.4 after 16 hours of fermentation, 5.2 after 40 hours, and 5.0 after 64 hours. These pH levels were within the ranges recommended by industry-developed good manufacturing practices.[10] The plant ended fermentation after approximately 88 hours and moved the salami to an environmentally controlled drying room to dry for approximately 36 days. Routinely collected monitoring data indicated that the temperature and humidity ranges used during the production of lot X were within those prescribed by the plant. The Food Safety and Inspection Service Microbiology Division tested four *E. coli* O157:H7–positive brand A salami samples and found the internal pHs (range = 4.9 to 5.0), salt content (range = 3.7% to 3.9%), and moisture–protein ratios (range = 1.80

TABLE 1—Estimated Infectious Dose of *E. coli* O157:H7 from Dry Fermented Salami Consumed by Four Case Patients in the 1994 King County, Washington, Outbreak

Case Patient	Age, y	Sex	Reported Amount Consumed[a]	Amount Consumed, g[b]	Estimated No. *E. coli* O157:H7 Organisms Consumed[c]
A	5	Female	8–10 slices	48–60	19–24
B	4	Female	1–2 slices	6–12	2–5
C	24	Male	3 slices	18	7
D	4	Female	2–4 oz	57–113	23–45

[a]Case patients reporting the quantity of salami consumed to Seattle–King County Department of Health (M. Davis, written communication).
[b]Conversions from slices to grams used the median value of 6.0 g/slice reported by the Food Safety and Inspection Service.
[c]Calculations based on the highest contamination level detected (most probable number = 0.4 organisms per gram).

to 1.86) to be within normal ranges specified by the plant for its dry fermented products.

The dry fermented slicing salami was protected from cross contamination by external casings until the casings were removed by hand on October 4, 1994, in preparation for slicing. The following day, the salami was sliced with a mechanical slicer and packaged in 3-lb packages under one of three different brand labels (brand A, brand B, or brand C). Although the slicing operation was automated, three employees touched the salami contained in each package during the slicing and packaging process. We interviewed 15 (94%) of 16 persons who handled and sliced the brand A salami during the first 2 weeks of October. These individuals were unable to recall specific events related to the production of the implicated salami, but they indicated that no significant changes in procedures or personnel had occurred during the last 6 months of 1994. Also, they reported no gastrointestinal illnesses during the first 2 weeks of October 1994, and these reports were compatible with plant sick leave records. Consistent information was provided by management, supervisors, current workers, and two former employees.

Of the four types of salami produced on August 25, 1994, only samples of the presliced and calabrese salami were recovered from retail stores and the plant warehouse. Seven samples of presliced brand A salami were collected from retail stores epidemiologically linked to the outbreak; all were *E. coli* O157:H7 positive. *E. coli* O157:H7 was not isolated from the calabrese salami. The only type of lot X salami remaining in the plant warehouse on December 3, 1994, was presliced salami bearing the brand B label. Thirty-two intact packages of brand B salami were sampled for *E. coli* O157:H7; one (3.1%) was positive. Patient isolates, product isolates collected at the retail level, and the isolate from the brand B salami collected at the warehouse had identical banding patterns when analyzed by pulsed field gel electrophoresis. The most probable number of *E. coli* O157:H7 organisms contained in positive salami samples was uniformly low: less than 0.3 organisms per gram (three samples) and 0.4 organisms per gram (one sample). The estimated infectious doses for the four case patients who ate known quantities of brand A salami were in the range of 2 to 45 bacteria (Table 1).

Discussion

The findings of our investigation suggest that the methods used to produce the lot X salami were typical of those used in plant S throughout 1994. Although differences in the processes used by manufacturers exist, the production methods used in plant S are representative of procedures used industrywide to produce Italian-style salami. Because the plant participated in the Food Safety and Inspection Service Total Quality Control Program, detailed records regarding production, sanitation, and quality control practices had been collected on a daily basis. These records, the results of Food Safety and Inspection Service inspections, and the information gathered from plant S food handlers all indicate that the production methods used to produce brand A salami complied with existing regulations and recommended good manufacturing practices.[10]

E. coli O157:H7 with pulsed field gel electrophoresis patterns identical to those of patient isolates were recovered from intact packages of brand A and brand B, indicating that product contamination did not occur at the retail level. The possibility that the salami was contaminated with *E. coli* O157:H7 during the slicing and packaging process in the plant could not be ruled out. Because the outbreak was not recognized until several months after the production and slicing dates, food handlers may not have remembered events that resulted in contamination of the salami. However, the consistency of information obtained from our environmental evaluation, previous Food Safety and Inspection Service inspections, and food handler interviews indicated that this was, in many ways, a model plant that met or exceeded sanitation requirements, maintained good separation of raw and finished products, and had a stable, experienced work force. The data from our investigation provided no evidence to suggest that postprocessing contamination occurred.

E. coli O157:H7 may have been present on raw meat that was brought into the plant and subsequently survived the fermentation and drying steps involved in salami production. One laboratory study, published in 1992, indicated that *E. coli* O157:H7 can survive a typical dry fermentation process: when 10^4 *E. coli* O157:H7 organisms per gram were inoculated into salami batter, approximately 10^2 organisms per gram survived processing.[11] Raw meat products delivered to plant S were not microbiologically tested, so we could not determine the level of bacterial contamination that might have been incorporated into lot X salami. US Department of Agriculture studies have found that *E. coli* O157:H7 is rarely present in beef (0.2% of all beef carcasses sampled).[12] However, when present, *E. coli* O157:H7 may occasionally be present in high numbers: in one recent outbreak, counts of 10^3 *E. coli* O157:H7 per gram of meat were found on one carcass (Food Safety and Inspection Service, unpublished data, 1994). If trimmings from a carcass with a similar level of contamination had been introduced into one or more batches produced on August 25, 1994, the levels of contamination found in the brand A salami could have resulted.

Data are unavailable to estimate the extent of the contamination within lot X. Although all brand A samples from lot X tested were culture positive, all brand A samples had been collected from outbreak-

linked retail stores. Among brand B samples (which came from the same production lot), only 1 of 32 unopened packages collected from the company warehouse was culture positive for *E. coli* O157:H7. More than 800 additional samples from other production lots were tested for the company by a commercial laboratory; all were reported to be negative for *E. coli* O157:H7. These data do not suggest that widespread contamination existed in the plant and are compatible with the hypothesis that a limited amount of contaminated meat was introduced into one or more of the 310-lb batches of slicing salami included in lot X.

E. coli O157:H7 has emerged as a major human pathogen during the past decade. The number of cases appears to be increasing, as is the frequency of complications of infection (e.g., hemolytic uremic syndrome).[12] Although the majority of reported *E. coli* O157:H7 outbreaks have been associated with consumption of ground beef,[13,14] the organism's tolerance of acid conditions[15,16] and apparent ability to cause human infection after ingestion of fewer than 50 organisms are properties that may allow dry fermented meat products to serve as vehicles of infection. Traditional drying and fermentation methods can be modified to include bacteriocidal processes (e.g., cooking or treatment with irradiation) that would improve product safety; however, inclusion of a cooking process could alter characteristics (e.g., texture) that consumers expect of salami-style products. As a result of this outbreak and the findings of the previously reported laboratory study,[11] the US Department of Agriculture is requiring that manufacturers of dry fermented meat products in the United States determine how effectively their processing methods eliminate *E. coli* O157:H7 from their final products. As these studies are completed, we should have a better understanding of the degree of safety provided by existing fermentation and drying processes. □

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