Review

Foodborne Illness Outbreak Associated with a Semi-Dry Fermented Sausage Product

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ABSTRACT

A state department of health reported an increase in cases of human salmonellosis and found an association (odds ratio 20; 95% confidence interval 4 to 131) between Lebanon bologna consumption and 26 confirmed cases of Salmonella typhimurium. Based on this evidence, the manufacturer initiated a voluntary recall of product in commercial channels and added additional safety measures to their manufacturing processes. The USDA’s Food Safety and Inspection Service promptly issued a recall notice to consumers stating that the suspected product should be returned to the place of purchase. A team of federal investigators concluded that at the time of the outbreak S. typhimurium may have survived the process used by the manufacturer if present in high numbers in raw beef (greater than 10^4/g). Additionally, the investigators concluded that other manufacturers of similar product needed to add controls to their processes used to manufacture a semi-dry fermented sausage in order to ensure the safety of the final product.

Key words: Salmonella typhimurium, Lebanon bologna, foodborne illness, process control

In October of 1995 a state department of health issued a public notification to consumers about possible salmonellae contamination in Lebanon bologna. This warning was based on an increase in Salmonella cases in the state and a preliminary case-control study showing a strong statistical association (odds ratio 20; 95% confidence interval 4 to 131) between 26 confirmed illnesses and exposure to Brand X Lebanon bologna. Salmonella typhimurium was isolated from opened packages of Brand X Lebanon bologna taken from the refrigerators of several ill persons in separate households. The contaminated bologna was purchased from at least five different retail outlets.

Nontyphoidal salmonellosis is a leading cause of foodborne illness in this country and did not emerge as a public health problem until after World War II. S. typhimurium accounts for 25 to 30% of human isolates and its resistance to antimicrobial agents is an increasing public health concern (3).

The manufacturer of the product began a voluntary recall of the suspected product soon after the state department of health established the association between the illnesses and the Brand X product. The Food Safety and Inspection Service (FSIS) promptly issued a recall notice informing consumers that certain brand names and package sizes of Lebanon bologna should be returned to the place of purchase.

FSIS’s Office of Public Health and Science assembled an investigation team that included representatives from its Emergency Response Division, Microbiology Division, and from Field Operations the Processing Operations Staff. The team’s objective was twofold: first, determine if a breakdown in the plant’s processes resulted in Salmonella contamination of the finished product; second, determine if there was a food safety hazard inherent in the manufacture of Lebanon bologna.

DESCRIPTION OF THE PRODUCT AND PROCESS

Lebanon bologna is a traditional, semi-dry, fermented beef sausage. The safety of the product depends on a combination of factors including salt content, presence of a curing agent (nitrite or nitrate), time and temperature in the smokehouse, moisture level, and an active fermentation culture that lowers product pH. Since the heating temperature alone that is applied to the product at the time of smoking is not sufficient to destroy vegetative pathogenic microorganisms, it is important that all other critical factors are achieved.

Three basic methods of fermentation are used in Lebanon bologna manufacturing: traditional, inoculum beef, and the direct addition of starter culture to the meat. The traditional method of manufacture relies on growth of lactic acid bacteria normally present in meat. The inoculum beef method uses a starter culture added to a known weight of

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raw meat, then all or part of the mixture is added to the meat formulation after the coarse grinding. The direct starter method adds the starter culture directly to the coarse-ground meat block during formulation. Sodium nitrite and sodium erythorbate are often added when using the direct starter method instead of potassium nitrate.

Lebanon bologna is produced by at least eight federally inspected establishments in the United States. Each produces between 200 and 100,000 pounds of Lebanon bologna weekly. The manufacturer of the Brand X product operates two plants: one facility of approximately 3,000 square feet and the other measuring more than 20,000 square feet. The company employs 65 persons and produces annually more than 5,000,000 pounds of Lebanon bologna as its sole product. The traditional method of fermentation was used for 70% of the product produced by the manufacturer of the suspected product during the time that the outbreak occurred.

The following is a description of the procedure used to produce Brand X Lebanon bologna. The smaller plant received fresh, presalted (2%), federally inspected boneless beef in 907-kg units (2,000-pound containers). Upon receipt, the meat was further inspected for proper temperature, presence of foreign materials, excess fat, and pockets of salt. Additional salt, spices (exact formulation is proprietary), and potassium nitrate (target level 156 ppm) were mixed with the meat block (block size is proprietary), then the mixture was coarsely ground. No rework was incorporated. The product was transferred to plastic tubs and aged at a temperature less than 7°C (45°F) for 10 to 14 days. The aged meat mixture contained about 3.3% salt at a pH of about 5.9.

The salt content of the beef is critical; too little and spoilage may occur, though the pH drops sufficiently; too much salt and the lactic acid bacteria do not grow to populations sufficient to reduce pH (7). Aging is necessary when relying on the natural flora present in the meat to produce the required acidity. Acid production does not reliably occur in bologna made from unaged beef without a starter culture (7). During aging, lactic acid bacteria must reach about 10^4 CFU/g for adequate acid development. Aging also promotes the reduction of nitrate to nitrite by micrococci and inhibits the growth of pseudomonads and other spoilage organisms.

The aged meat was transferred to the larger plant for final grinding and stuffing. The stuffed product was loaded stick by stick into tall wooden smokehouses fueled solely by hardwood and smoked to a final product temperature of 43°C (110°F) which takes between 52 and 72 hours. Different sized product was contained in each smokehouse. Each smokehouse held 11,000 to 15,000 pounds of product. Moist smoke, produced by smoldering hardwood chips positioned on a metal plate over the fire pit, saturated the interior of the smokehouses.

Optimally, as the product temperature reaches about 18°C (65°F), the pH begins to drop due to production of lactic acid by bacteria present in the meat. The pH should continue to drop to about 4.5 as the product reaches a final temperature of about 43°C (110°F). Organoleptic tests (appearance and firmness) were conducted on the product to determine when the fermentation phase was complete. According to company officials, the time in the smokehouse ranged from 52 to 72 h.

The product was unloaded from the smokehouses, stick by stick, and transferred to the final processing area where the smoke-blackened netting was removed and excess soot was wiped off the product. The Brand X product was available to consumers in several different forms: sliced in consumer vacuum packages, 0.7-kg small chubs (1.5 pounds) and 4.5-kg large chubs (10 pounds), and whole and half chubs. The plant produced the bologna under several different names and bore varying sell-by dates dependent on the customer's specifications.

According to FSIS laboratory tests on similar product in commerce, the finished product had a moisture content between 60 and 63%, protein content 17%, fat 5 to 11%, salt 3.0 to 3.25%, a_0 0.95 to 0.97 and a pH between 4.4 and 4.7.

**PROCESS ANALYSIS USING MODEL DEVELOPED BY THE AGRICULTURAL RESEARCH SERVICE**

The Agricultural Research Service (ARS) developed a predictive microbial modeling program to estimate the effects of multiple variables on the growth or survival of foodborne pathogens. The model calculation was for a single point in the process, not an integrated approach, and was based on a broth culture system, not on a meat or fermented sausage product, nor was it specific for *S. typhimurium*. The model was useful to show the importance of critical control factors, such as pH, and their effect on deactivation of salmonellae (1).

The model included nonthermal inactivation models for several pathogenic bacteria including *Listeria monocytogenes*, *Salmonella spp.*, *Escherichia coli O157:H7*, and *Staphylococcus aureus*. ARS produced the program by using the results obtained from a brain heart infusion broth culture system whereby organisms were exposed to various parameters (temperature, pH, salt, nitrite, atmosphere). The program established a 4-log reduction model for salmonellae.

Processing parameters of Brand X Lebanon bologna were used as variables in the ARS predictive model. Results obtained by the model are shown in Figure 1. The figure shows that the 4D lethality at 43°C (110°F) product temperature and a nitrite concentration of 120 ppm (maximum allowed in model) varied according to pH and salt concentration. Generally, as pH increased and salt concentration decreased, the hours needed to obtain a 4-log reduction in salmonellae increased. Note that small changes in pH greatly affect the time needed to achieve a 4-log reduction. For example, at a pH of 4.8 and a salt concentration of 3%, 58 hours were required to achieve a 4-log reduction in salmonella. At pH 5.0 and a salt concentration of 3%, 80 hours were needed to achieve the same reduction in salmonellae.

**INDUSTRY PROCESSES**

An FSIS investigative team visited many of the Lebanon bologna producers to learn about differences and
similarities in the production of the product among producers. The investigators discovered wide variances in production methods. A discussion of the differences follows and is organized by process flow and is focused on critical areas.

Receiving

All producers received raw beef that was at least 90% lean. One producer used a small portion of beeck meat in the meat block. The meat was received in several forms: 907-kg containers (2,000 pounds), frozen boxed beef, 181-kg barrels (400 pounds), or directly from the boning table. Several producers used both domestic and imported beef. One producer conducted microbial tests on the incoming raw beef where samples were tested for salmonellae, E. coli O157:H7, and aerobic plate count. All producers that received fresh beef began to process it within 5 days. No producer reported receiving presalted meat. However, two producers salted the raw beef and held it at refrigerated temperatures before further processing, one for two weeks and one for 2 to 3 days.

Formulation

After coarse grinding of the raw beef, ingredients were added depending on the type of Lebanon bologna to be made. Two general types were produced, sweet and regular. The sweet Lebanon bologna differed only in respect to added sugar, or in one case brown sugar. All producers added between 2.5 and 3.5% salt. All spices were formulated by spice companies and added by scooping from a bulk container or added directly to a meat block from individual packets. Rework, from sliced ends and pieces, was used by two producers.

Different cures and cure mixtures were used. Some producers used a “modern cure” that was composed solely of sodium nitrite in a salt carrier. Others used a combination of sodium nitrite and sodium ascorbate or sodium erythorbate. One producer used only sodium nitrate.

The end result of nitrate and nitrite is the same (nitrosohemochromogen); however, nitrite reacts quicker, and less is required for color stabilization (5). The salts of ascorbic and erythorbic acid accelerate the reduction of metmyoglobin to myoglobin, thereby increasing the rate of curing. They also react chemically with nitrite to increase the yield of nitric oxide from nitrous acid and, if present in excess, serve as an antioxidant. Products with ascorbate or erythorbate typically go directly into the smokehouse after stuffing.

All producers used 156 ppm NaN0₂ as a target level for the incoming curing agent. One producer added liquid smoke to the product at formulation and rubbed it on the casing after stuffing. With only one exception, all producers added a lactic acid starter at formulation. One producer relied on natural fermentation, thus did not add a starter culture at formulation, but used a smoking and fermentation phase of 6 days (144 h).

Stuffing

All producers used an artificial fibrous type of casing generally of two sizes: one of a larger diameter of 10 to 13 cm (4 to 5 in.) and 91 to 101 cm (36 to 40 in.) in length and a smaller chub that measured 2.5 to 5 cm (1 to 2 in.) in diameter. At least two producers had a metal detector at the stuffer. There was generally little time (less than 24 hours) between stuffing and placement of product in the smokehouse.

Smoking and fermentation

The most discernible difference among producers of Lebanon bologna was seen in the smoking and fermentation phase of the process. The smokehouses varied in type of construction, type of controls, and type of applied heat. Several smokehouses were made of wood and detached from the main plant. They depended on the natural flow of hardwood-heated air with no or minimal temperature controls and were subject to varying weather conditions. Others were constructed of stainless steel, heated by forced-air gas, and equipped with automatic control of both temperature and humidity.

Figure 2 shows the heating profile of several producers. The heating curves represent the approximate product temperature with the end coinciding with the final product temperature. Note that the final product temperatures ranged from 43 to 57°C (110 to 135°F). The times in the smokehouse ranged from 24 hours to six days. All but one producer used sawdust or wood chips as a smoking agent; the one exception used only liquid smoke.

Most producers moved the product in and out of the smokehouse on metal carts, while a few loaded and unloaded the smokehouse stick by stick. Several producers measured the length of the fermentation phase by taking a pH measurement and ended the phase only if the pH was 5.0 or below. Other producers used only organoleptic checks such as firmness, appearance, and in one case, taste, to decide the end of the smoking and fermentation phase.
Figure 2. Fermentation time and temperature for Lebanon bologna of several manufacturers.

Package and label

Most, but not all, provided their product for sale in whole or portioned rolls, and in consumer packages of sliced product. All but one producer used vacuum packages on the final product. All but one producer placed “Keep Refrigerated” on the consumer label. The one producer that did not place “Keep Refrigerated” on the label did not conduct moisture tests, such as moisture/protein ratio (MPR) or aw, on the final product. All but two producers placed a packaging and/or sell-by date on their product. Sell-by dates ranged from 70 to 180 days. This coding, if consistent, simplifies trace-back of product to a certain batch or small number of batches, when necessary.

Finished product testing

Two producers tested and recorded results of the finished product for pH, moisture, and level of microorganisms. One company assayed specifically for E. coli O157:H7 in the finished product.

Cross-contamination controls

The degree of control of cross contamination between raw and finished products varied among the producers. Several producers had written procedures that dictated stringent controls to help prevent contamination of the finished product by a raw product. This included employees wearing color-coded coats and using plastic gloves and sleevedware, separate finished product cooling areas, and strategically located hand-washing facilities and foot baths. However, many of the Lebanon bologna producers had no written controls to reduce the risk of cross contamination of the finished product.

Record keeping

Two plants kept records showing the time and temperature of the smoking and fermentation process, the pH achieved, and the moisture content of the product. One plant kept records of the final temperature of the product, but no pH data. For the most part, adequate records did not exist in all plants that could verify that a particular batch of product achieved the proper pH, time and temperature of heating, and final moisture content.

FEDERAL INSPECTION

The Performance Based Inspection System (PBIS) is a computerized system that schedules inspection tasks for in-plant USDA inspectors, collates the national results, and provides feedback to managers of the program. Inspection tasks are taken from the Inspection System Guide (ISG). The ISG is divided into 12 process categories: facilities and equipment, sanitation, slaughter, pest and rodent control, receiving, processing, labeling, finished product storage and shipping, restricted product, inedible product handling, product analysis, and exports.

Inspectors may be assigned solely to one plant or may cover several plants on a patrol assignment. The two plants producing the Brand X Lebanon bologna are on a patrol assignment covered by an inspector with 22 years of experience. The inspector’s schedule allows for about 25% unscheduled time when the inspector can perform unscheduled inspection tasks chosen from the ISG.

Approximately 1,000 inspection tasks are done annually in each of the two plants involved in the production of the Brand X Lebanon bologna. Sanitation tasks account for more than 50% of the inspection tasks done in the two plants (Fig. 3). In the finishing plant (larger plant), labeling and packaging accounts for the next highest percentage of the inspection tasks performed (12%), while processing accounts for only 10%. In the raw material receiving plant (smaller plant), processing accounts for the second highest area of inspection tasks performed (24%).

An FSIS monitoring plan is developed for every USDA-inspected processing plant. The monitoring plan is made up of applicable inspection tasks taken from the ISG.

Figure 3. USDA inspection emphasis in two plants of the Lebanon bologna manufacturer of the suspected product.
The monitoring plan for the finishing plant shows that only one inspection task is used to monitor the process through grinding, aging, stuffing, smoking, and transfer of the finished product to the packaging area. No deficiencies were recorded for this task during the time that the Brand X Lebanon bologna was manufactured.

The monitoring plan for the finishing plant lists one product analysis task. Data from January through October 1995 show that seven samples were analyzed for E. coli O157:H7 and three samples were analyzed for staphylococcal enterotoxin. All results were negative. No tests were conducted for salmonellae.

**PROCESS CHANGES BY THE MANUFACTURER OF THE SUSPECTED PRODUCT**

The company made significant changes in their manufacturing process since the outbreak occurred. During the investigation of this outbreak, plant management conducted a survey of their establishment for salmonellae. The survey, performed by a private laboratory consultant, consisted of collecting samples throughout both the receiving plant and the finishing plant. The samples were analyzed for salmonellae using AOAC approved methods. Only one sample was positive, and it was taken from a floor drain in the receiving plant. After the survey, the plant was thoroughly cleaned, according to the plant management.

The company now receives unsalted raw beef which allows absolute control of one of the critical safety factors for the production of Lebanon bologna, i.e., the salt content.

The company abandoned the traditional method of fermentation and is now using the inoculum beef and direct starter culture methods exclusively. A portion of inoculated beef is added to the formulated meat block that is then aged. This change ensures that the bacteria needed for lactic acid production are present in the raw material in adequate numbers, thus providing better control over another critical safety factor, acid production.

Before the outbreak, the company heat treated only specific brands of bologna to 49°C (120°F), as required by the customer's specifications. The company is now experimenting with heat treating all of their product to an internal temperature of 49°C (120°F). This change will add an extra degree of safety to their product, as an increase of 5.6°C (10°F) will increase the lethality of the process resulting in a greater reduction of pathogens, including salmonellae.

The company is now conducting both organoleptic and quantitative measurements of critical factors to decide when the product is ready for sale. Written documentation is now being kept for each smokehouse showing the product temperature, ambient air temperature, and product pH throughout the process. Computer-linked automatic recording devices showing process time and temperatures have been added to the smokehouses. These changes ensure that the proper pH and processing times and temperatures are attained. Records are available for review.

The company began a standardized sell-by date or shipped-on date code procedure. All vacuum-packed product bears a 120-day sell-by date and/or a shipped-on date, depending on the customer requirements. These dates are calculated from the day of slicing or shipping. A production control date is placed on all bulk-type product.

**CONCLUSIONS AND RECOMMENDATIONS**

Salmonella typhimurium is the Salmonella most frequently isolated serotype from human and nonhuman sources (4). This pathogen can be eliminated from raw beef during the manufacture of Lebanon bologna if certain critical factors are met during processing (8). Since the product is not heat treated to temperatures that would kill or disable vegetative pathogenic microorganisms that may be present in the raw meat, the producer must follow a combination of process controls to ensure that critical factors are met in order to obtain a pathogen-free product.

Due to the inability to pinpoint an exact production lot, a lack of documentation of the critical factors met for each lot, and the absence of microbiological sampling data during the time frame when the suspected product may have been produced, it could not be determined if a process failure had occurred or if high numbers of S. typhimurium were present in the raw beef. Research shows that when raw meat contains high numbers of S. typhimurium, 3 days (72 hours) of fermentation are not adequate to destroy all of the microorganisms when using natural fermentation and aged beef in Lebanon bologna manufacture (8). Therefore, S. typhimurium could have survived the process that was in use by the manufacturer when the outbreak occurred if the organism was present in high numbers (>10⁴/g) in the raw beef.

As a result of this outbreak, the manufacturer of the Brand X Lebanon bologna made significant changes to its process. The firm voluntarily instituted process controls that decrease the chance of a process failure and increase the likelihood that a process failure would be detected, should it occur. For example, the manufacturer now uses a starter culture and brings the final product temperature up to 120°F rather than 110°F. This temperature difference alone adds at least one extra log reduction in S. typhimurium if present (8).

Research also shows that 3 days (72 hours) of fermentation are adequate to destroy high levels of S. typhimurium when a commercial starter is used.

However, the investigation found that a wide variation still exists in industrywide practices and controls. This salmonellosis outbreak, along with other recent foodborne outbreaks involving similar products, e.g., E. coli O157:H7 associated with dry fermented salami (9) and S. typhimurium associated with beef jerky (2), demonstrates the importance of process control during the manufacture of fermented and/or dried ready-to-eat products. In the past, control of the critical factors relied on a “rule of thumb” approach with almost no documentation. Therefore, the investigators concluded that process controls for all producers of fermented and dry-cured products should be strengthened and mandated. These added process controls include the following.

1. Control and document critical factors. Critical factors include pH, cure and salt content, moisture, and/or any...
other intrinsic factors that dictate the safety and stability of the product. Controls include developing written procedures, documenting daily events, outlining corrective action, and verifying critical production activities. In the past, this approach has proved successful for decreasing the incidence of foodborne disease attributed to specific types of meat and poultry products. Examples include control of botulism in canned food, control of *E. coli* O157:H7 in cooked beef patties, control of *L. monocytogenes* in sausage products, and control of salmonellae in cooked roast beef products. FSIS’s hazard analysis and critical control point regulation (10) mandates this type of control of critical areas during the production of all meat and poultry products.

Natural fermentation is an unreliable method for fermented meat production. It offers minimal safety and lack of uniformity in the finished product and should be eliminated (4). If natural fermentation is used, the processor should incorporate stringent controls to ensure that critical factors are met and that the final product is free of pathogens.

Process controls should include methods that minimize the risk of cross contamination of the finished product. For example, employees unloading a smokehouse or handling finished product should not have previously contacted raw product without changing garments and washing and sanitizing hands. In the past, producers of fermented and dried products were exempt from the sanitation requirements for ready-to-eat products. Ready-to-eat product sanitation requirements now apply to producers of semi-dry and dried fermented products, and all producers should adhere to the requirements.

2. **Use quantitative measurements.** Quantitative measurement of process controls should be in place and recorded for all critical factors such as pH, moisture content, etc., during processing. In the past, many firms relied on organoleptic tests, in which product is visually inspected, touched, even tasted, to determine the end of the process. Process controls should be added which dictate the method by which measurements of smokehouse temperature and product pH are taken. Due to the traditional construction, location, and heating methods of the wooden smokehouses, temperature and humidity are difficult to control, and thus variability exists. Adding to this variability is the mixing of different sizes of product in the smokehouses during a heating cycle. Instructions to operators of the smokehouses should be available describing where measurements should be taken and of which products.

3. **Code product.** Product codes should be applied to all finished product. The code should identify the lot, and the lot’s records should show that the critical factors were met during the process.

4. **Validate process.** Since Lebanon bologna producers do not use identical smoking and fermentation processes, it is essential that each process be validated by a qualified, independent source. For example, time and temperature during the smoking and fermentation phase differ from producer to producer. Several producers have started the validation process and have found that their present process meets or can easily be modified to assure the criterion that a 5-log reduction in pathogenic bacteria be met. For example, a 5-log reduction in *E. coli* O157:H7 has been found to be achieved by fermenting at 43°C (110°F) to a pH of 4.6 and holding at 43°C (110°F) for at least 4 days (7), criteria which were in use by some processors previous to this outbreak.

**REFERENCES**


10. USDA. 1996. Pathogen reduction; hazard analysis and critical control point systems. 9 CFR 304, inter alia.