Innovation for Microbial Pathogen Control in the Supply Chain for Hamburger Patties

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Microbial pathogen control in hamburger patty production poses several challenges. Grinding operations typically take raw beef trimmings from multiple sources and mix these inputs together to make patties. Meat trimmings may carry high pathogen loads because of how they have been handled and because they have multiple exposed surfaces. The grinding operation itself disperses any pathogens present on the trimmings throughout the ground product, and there is opportunity for those pathogens to multiply in the subsequent supply chain. Designing testing protocols for detecting sporadic pathogen loads in high volumes of product is a challenge, as is getting quick results on which to base management decisions.

This case study focuses on the development of the Bacterial Pathogen Sampling and Testing Program by the Texas American Foodservice Corporation (Texas American) in collaboration with four other entities: the Jack in the Box restaurant chain, one of Texas American's major customers; Qualicon, a unit of DuPont Company; the Public Health and Science Office of the U.S. Department of Agriculture's Food Safety and Inspection Service; and the National Cattlemen's Beef Association.[1] The story of the Bacterial Pathogen Sampling and Testing Program is one of a series of factors coming together at one time. These included a demand for increased pathogen control by a major buyer of hamburger patties, the competitive interest of the supplier in building a reputation for quality control, and the technological opportunity afforded by the interest of an input supplier in adapting its improved testing technologies to the food industry. The outcome was a significant food safety innovation.

The Bacterial Pathogen Sampling and Testing Program is a process innovation combining a new sampling protocol/management system for *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* sp. and a new application of a patented testing technology to hamburger patty processing lines. The process innovation has resulted in a product innovation: hamburger patties with consistently low levels of pathogen contamination. This case study sheds particular light on the nature of appropriability for process innovations aimed at improving the safety of food products. It also sheds light on the set of incentives generated in the supply chain when operational change is necessary to assure a higher and more reliable level of food safety.

The 1993 *E. coli* O157:H7 Outbreak Catalyzed Changes at Texas American Foodservice

Texas American is a unit of the American Foodservice Corporation, a privately owned company that operates three plants in the United States (table D-1 presents background on the general characteristics of Texas American). American Foodservice Corporation is one of the largest independent ground beef producers in the United States. The main product of Texas American is frozen hamburger patties, supplied mostly to national and regional fast food companies, such as Jack in the Box. At the time of the 2001 interview, Texas American had 430 employees and processed 150 million pounds of ground beef annually, all of which was sold within the United States.

When Texas American began producing hamburger patties in the mid-1980s, there was no significant publicity or regulatory policy around ground beef and microbial food safety risk. Nevertheless, in the early 1990s, it began to focus on the effects of improving quality control and food safety. These effects included improving external failures (product rejections, product returns, liability, threatened loss of supply contracts, and a threatened increase in USDA inspection oversight), as well as internal process failures that resulted in product losses.

In 1992, Texas American hired a leading expert on quality control, Timothy Biela, to assist it in the redesign of its pathogen control system. Shortly thereafter it began investigating clinical microbiological testing technologies, such as Polymerase Chain Reaction (PCR) testing,

[1] Information on this innovation was obtained in interviews with Timothy Biela (Texas American Foodservice) in 2001 and 2002 and with Dr. David Theno (Jack in the Box) in 2001 and 2002. (For survey format see Salay et al., 2003.)

Table D-1—General characteristics of Texas American Foodservice Corporation, 2001

Main activity	Ground meat producer, two facilities in Fort Worth, Texas
Main products	Ground beef, 150 million pounds annually
Number of employees	430 employees (under USDA FSIS classifications, this is a small (< 500 employees) operation)
Main market segment	85% of production is frozen patties for commercial fast food, other markets include casual dining, retail, and wholesale
Exports	No exports
Parent Company: American Foodservice Corporation	5 plants in the United States with total production of 280 million pounds of ground beef annually
Ownership	Privately owned corporation

that could be adapted for use in monitoring pathogens in the hamburger supply chain.

The need for better pathogen control in the hamburger patty supply chain was brought to widespread attention in the United States by the 1993 Jack in the Box foodborne illness outbreak associated with inadequate cooking of hamburger patties that were contaminated with *E. coli* O157:H7 (see box "Pathogen Reduction and Hazard Analysis and Critical Control Point Program," p. 15). In the wake of the 1993 outbreak, Jack in the Box instituted quality control programs reaching over all aspects of company operations from procurement through in-store cooking and handling to the consumer. First, the company hired a new manager with food safety experience in the poultry industry, Dr. David Theno, to head its safety program. Next, the company suspended all existing contracts with hamburger patty suppliers and designed new contract specifications. Only two companies, one of them Texas American, met the demands of the new contracts.

Texas American was in a good position to respond to the call from Jack in the Box for producers who could supply hamburger patties that met strict quality standards. It was able to move quickly after the 1993 outbreak because it had already begun developing a new systematic approach to pathogen control and had begun investigation of testing methodologies.

Development of New Sampling and Testing Protocols: Innovation Through Collaboration

The Bacterial Pathogen Sampling and Testing Program is a process innovation combining two parts: a new sampling protocol/management system and the new application of a patented testing technology to hamburger patty processing lines. Safety in the Texas American program is controlled through strict testing to assure that standards are met in raw materials, in bulk product coming out of the grinder, and in finished patty products. Though Texas American maintains strict temperature control and cleaning regimes within the plant, it does not include a kill step, such as steam pasteurization or irradiation, in its production lines. The key critical control point in its safety system is the quality and temperature of raw materials coming into the grinding plant (most of the actual activities necessary to reduce pathogen loads occur in the plants of the raw material suppliers).

The successful development of the Bacterial Pathogen Sampling and Testing Program hinged on the development of a well-targeted sampling protocol and a good testing technology (see box, "Texas American Foodservice Corporation Bacterial Pathogen Sampling and Testing Program" for the major elements of the innovation and the appendix to this chapter for an overall timeline for the development of the innovation). Sampling protocols are of great importance to the management of pathogen risk because testing every product is not economically feasible, particularly since the pathogens of interest tend to be sporadic and at a low level (Pruett et al., 2002).

The Texas American sampling protocol is designed to manage risk to an acceptably low level. Trimmings entering the plant are sampled based on type, supplier, and supplier performance but not less than every 100,000 pounds, which for most raw material suppliers is daily. If lots test higher than standards, the supplier is notified immediately and testing is intensified. All raw materials are routinely screened for Aerobic Plate Counts (APC), generic coliforms, generic *E. coli*, Staphylococcus aureus, *Salmonella*, and *Listeria monocytogenes*. These routine test results are reported to suppliers and reviewed with them monthly.

Samples are next taken at the final grind head, where each batch of 3,000 pounds of hamburger is tested for *E. coli* O157:H7. Finally, samples of the finished prod-

Texas American Foodservice Corporation Bacterial Pathogen Sampling and Testing Program (and description of additional quality control procedures)

Element of Protocol

Temperature monitoring of incoming combo bins (2,000 lbs.) of beef trim; reject if temperature is above 40ºF

Combo bins sampled based on type, supplier, and supplier performance record; sampled not less than every 100,000 lbs.; most raw material lots sampled daily

Test results given to supplier monthly for all lots tested; if lots test higher than standards, supplier is notified immediately and testing is intensified, monthly review of supplier performance on microbiological criteria and in-plant audits to assess compliance with Texas American standards with performance compared to that of other suppliers

Temperature control (40ºF) and inventory management system for combo bins, first-in-first-out, use by 5th day after boning

Samples are taken at the final grind head for each 3,000-lb batch of hamburger tested for *E. coli* O157:H7

Samples of finished products are taken from each process line every half-hour; half-hour samples are combined into "half shift" composites representing every 4 hours of production, tested for complete microbial profile (APC, coliform, *E. coli, Staphylococcus aureus, Salmonella* sp., and *Listeria monocytogenes*), individual backup samples for each half hour are tested only if composites show spikes or high counts

Rework procedures in place, internal failures (e.g., the patty does not meet specifications) are continuously reworked during the day with quantity of rework recorded for each batch, end of day rework is only used during the last hour of production on the next day (segregated by product), at end of week all remaining rework is destroyed

In-plant cleaning regime in continuous operation, monthly random pre-operational swab tests to verify the efficacy of cleaning procedures and monitor the environment for pathogens

Temperature control (less than 10ºF) for frozen patties

Continuous review of procedures and results; adjustment of operating procedures to address problems and opportunities for improvement

uct are taken from each process line every 15 minutes. Every hour, composites of the four samples are tested to detect *E. coli* O157:H7. These samples are also combined to make a "half-shift" composite, which is tested for an entire microbial profile (APC, coliform, *E. coli*, *Staphylococcus aureus*, *Salmonella* sp., and *Listeria monocytogenes*). If the half-shift composites show spikes or high counts, more tests are run on the backup samples, also collected every 15 minutes. At all testing points, action levels and actions to be taken if deviations occur are clearly defined.

The development of a good testing technology was as important as the sampling protocol to the success of the Bacterial Pathogen Sampling and Testing Program. Texas American believed that no one truly understood the incidence of contamination of beef with pathogens and that traditional microbiological testing methods were inadequate because they relied on culturing samples of meat, were not very sensitive, took time to run, and were not well defined for these organisms. Texas American started its quest for a new testing methodology by upgrading its own microbiology lab and investigating the availability of human clinical microbiological testing technologies that could be adapted for use in monitoring pathogens in the hamburger supply chain. It eventually settled on Qualicon's BAX™ detection system, which uses Polymerase Chain Reaction (PCR) technology to test for *E. coli* O157:H7 and other pathogens. The PCR technology allows users to target known DNA strands from specific organisms and is capable of detecting the target organisms at levels much lower than standard serological (cultural) methods.

The BAX™ technology was being used to detect human illness, but had not been used to detect pathogens in a food production setting. The application of the BAX™ test to food processing required Texas American to conduct experiments to assure that the tests performed as expected in the new setting. This need was an important motivation for Texas

American to engage in cooperative and collaborative arrangements in developing the program. For its part, Qualicon needed a partner to help validate the use of the PCR/DNA Bacterial Testing equipment and methods for meat products.

To properly validate and sell the efficacy of the technology, Texas American also solicited the involvement of several other groups. Until this time, there was significant speculation about the sensitivity of the PCR/DNA method and resistance to its use. It was also not well understood how organisms contained in food products (meat) reacted in typical grinding operations, for example, how they moved and the level of transfer from contaminated to non-contaminated meat. The validation collaboration involved parallel testing, using different methods, of a number of samples by Texas American by Silliker Laboratories (the largest independent commercial testing lab in the United States) and by USDA's Food Safety and Inspection Service (FSIS), through its Office of Public Health & Science (Pruett et al., 2002). Texas American funded its technicians, the microbiological assays, and data analysis. The National Cattlemen's Beef Association funded the testing by Silliker Laboratories. FSIS funded testing at FSIS labs.

Jack in the Box played an active role throughout the development of the Bacterial Pathogen Sampling and Testing innovation. Since Texas American sells unbranded product in intermediate markets, it must tailor its product to the specifications of its major potential customers such as Jack in the Box. When Texas American became a supplier, Jack in the Box was looking for partners who could work with it to overcome the limits of microbial pathogen control. Jack in the Box established standards and was involved in monitoring the quality of raw material suppliers and specifying plants approved to supply to grinding operations producing hamburger patties for sale to Jack in the Box (Jack in the Box signs essentially cost-plus contracts with its patty producers that cover the costs of quality control). The result was a close collaboration that evolved over time as both parties learned more about the systems required to assure food safety.

Interestingly, government regulation was not an obvious driver in the development of the innovation. In fact, though some USDA regulation was a stimulant to better management of risks, Texas American often found itself in the position of sharing its superior information with regulators or driving collaboration with FSIS. Regulatory and consumer developments in other countries were also not drivers for innovation by Texas American because the company sells only within the United States.

The successful collaboration of Texas American, Jack in the Box, Qualicon (DuPont), FSIS, and the National Cattlemen's Beef Association ultimately resulted in the Texas American Bacterial Pathogen Sampling and Testing Program. Texas American believes that this innovation has reduced by 80 percent the risk associated with distributing a raw product that can potentially contain organisms that can cause illness or death if consumed prior to proper cooking and preparation. The company has never had a recall of its products and believes that its program significantly lowers the risk of recall or negative publicity associated with foodborne illness outbreaks.

Texas American Leads the Way… and Appropriates the Benefits

Texas American appropriated the benefits of its process innovation through establishing a substantial lead over its competitors. Texas American did not believe that pursuing patents or secrecy was important to maintaining or increasing the competitive advantage it would gain from the innovation. Indeed, the collaborative nature of the innovation process, with strong involvement from Qualicon and Jack in the Box, which in turn would be working with other suppliers, probably made secrecy unworkable. In fact, Texas American and Jack in the Box have been very active in sharing the new approach with other members of the hamburger patty supply chain. They believe that the reputation of the entire industry, including their own, is on the line anytime poor quality control results in illnesses and outbreaks associated with hamburger products. Texas American's stance is to share its knowledge about the implications of organisms like *E. coli* O157:H7 with potential customers as well as with competitors.

The Texas American experience supports the idea that transparency of an innovation does not necessarily imply that it will be widely imitated. The complexity of the management systems and the discipline they require, along with continued innovative activity, have helped Texas American build and maintain a competitive advantage. In addition, given current market conditions, the costs of adoption are high relative to opportunities to market improved pathogen control.

Texas American's first-mover advantage is also maintained through the fact that it captured a significant share of the market for hamburger patties produced to a higher pathogen control standard. Its dominant position may discourage other firms. However, this could change if demand for higher quality control standards becomes more widespread among buyers.

Texas American has been able to reap numerous benefits from its food safety innovation—and its first-mover advantage. One of the major benefits is that Texas American has been able to shift from being a commodity producer selling on a week-to-week basis to being a contract supplier. This shift has allowed Texas American to improve its operational efficiency through better planning for capacity utilization, capital investment, spending plans, and other business activities.

Another benefit of the innovation is Texas American's ability to use its superior knowledge and expertise in the area of pathogen control to attract new customers. Texas American has enhanced its reputation with quality control, superior knowledge, and risk management skills it has built over a period of almost a decade. The company's sales increased approximately 5 percent annually after it implemented the innovation. Over the 3 years up to 2001, Texas American estimates that about 25-30 percent of its new sales opportunities occurred because of the innovation. The increase in sales has had the added important benefit of allowing Texas American to increase its utilization of fixed capital by 20 percent over the last 5 years.

Texas American also attributes significant savings and other financial benefits to adoption of the program. The superior knowledge about incidence rates and potential for product contamination that Texas American has gained through the program has enabled it to make better risk-management decisions regarding suppliers of raw materials. Texas American's understanding of which raw material suppliers have higher incidence levels and at what times of the year to expect positive test readings in different types of raw materials allows it to make better purchasing decisions. Avoiding high-risk raw materials leads to fewer product rejections and helps save money. Thanks to the Bacterial Pathogen Sampling and Testing Program, Texas American has been experiencing very few contamination incidents per year for *E. coli* O157:H7; in some years it has had none or one.

The benefits of the Bacterial Pathogen Sampling and Testing Program to Texas American have outweighed the costs of the innovation even though the costs of instituting the program involved significant initial expenditures. Texas American characterized the startup expenses as very high. In addition, there were high costs related to destruction of product in the early stages of the implementation. To contain some of these costs, Texas American worked with USDA to get approval of a system to identify sub-lots for purposes of testing and recall. Over time, costs have not increased, even though testing technology has become increasingly sensitive.

Texas American reports that costs are being controlled due to several factors. First, the development of the sub-lot system has reduced the amount of product that needs to be removed by pinpointing product that is contaminated. Second, the raw materials industry has reduced microbial contamination rates for incoming product under the Texas American program, since Texas American works with its suppliers to reduce contamination and the performance of the industry has generally been improving. Finally, Texas American has set a reasonable threshold level for the BAX™ tests of its finished, frozen hamburger patties. Texas American set the threshold level for product rejection to eliminate the possibility of outbreak and massive recall. The most sensitive BAX™ test for ground meat is extremely sensitive; it is able to detect 1 cell/125 grams of product. Using the lower bound of such a sensitive test could result in rejection of as much as 30-65 percent of product depending on the geographical source and time of year.

Current costs of the program are minimal now that the innovation has been in place for a period of years. Texas American estimates that the cost per pound of the system runs between $0.001 and $0.01, without significant increases in labor, raw material consumption, or energy consumption. To maintain a competitive edge, and its name as a food safety leader, Texas American continues to expend capital on research and development, with the bulk of these expenditures going to food safety improvements.

An Emerging Market for Food Safety Opens the Door to Food Safety Innovation

The Texas American case study illustrates the impact that the emergence of a market for food safety can have on the appropriability of food safety

innovation—and hence on innovation itself. In the Texas American case study, Jack in the Box, a highly knowledgeable buyer with the ability to test for and verify safety attributes helped spur the development of the market for food safety attributes. Jack in the Box, and a number of other fast food and restaurant companies, have a great deal staked on the continued good reputation of their brand names. Particularly since the 1993 *E. coli* O157:H7 outbreak, these companies have had strong incentives to expend the resources necessary to control for food safety. They also typically deal with a very small number of suppliers and maintain traceability systems that allow them to track the source of any problems. Thus the failures usually thought to exist in markets for food safety are mitigated to a significant extent by the nature of the supply chain for hamburger patties used in chain restaurants.

The development of demand for food safety in this market, in response to the need to manage risk, in turn increased the probability that a company that invested in innovation for food safety control would be able to appropriate benefits from that investment. For Texas American, the push by Jack in the Box to find high-quality hamburger patty suppliers offered the opportunity to intensify the company's new commitment to quality assurance with substantial certainty that its efforts would be rewarded with sales at prices that would recognize the company's quality achievements.

Texas American and Jack in the Box worked collaboratively over time to attain higher standards. Both companies were first motivated by the need for risk management to limit or eliminate the damage in reputation, sales, and liability stemming from inadequate quality control. Both companies have found that a reputation for quality has served as a foundation for growth. These companies have helped develop a market for food safety—and through their reputations as safety leaders, both have reaped benefits from supplying this market.

Appendix B: Time Line for the Texas American Foodservice Corporation Innovation

1985: Texas American plant starts hamburger patty production.

Early 1990s: Texas American becomes concerned about quality control and begins exploring new methods to improve quality assurance.

Mar. 1992: Timothy Biela, Director of Quality Assurance, conducts hazard analysis for bacterial, physical, and chemical hazards for Texas American hamburger patties.

Early 1993: Jack in the Box *E. coli* O157:H7 outbreak.

Mar. 1993: Biela and Texas American General Manager schedule meeting with Jack in the Box to discuss a strategy and program for supplying frozen hamburger patties to Jack in the Box.

Mar.-Apr. 1993: Contract negotiated with testing details and responsibilities for affected products specified in the contract.

May 1993: Texas American starts supplying Jack in the Box.

May 1993-1994: Texas American upgrades microbiology lab, writes specific operation procedures, develops new sampling and testing protocols, acquires equipment from Qualicon and other suppliers.

1993-1994: Validation of Qualicon testing protocols.

1994-Present: Continued refinement of sampling and testing program.

2000: Begins joint venture into retailing Modified Atmosphere Packing of ground beef products.

2001: Texas American opens a second plant in Texas.