Chapter 12

"From Farm to Fork": How Space Food Standards Impacted the Food Industry and Changed Food Safety Standards

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Most Americans give little thought to the safety of their food until they hear of an *E. coli* outbreak or a recall of their favorite item. They may be surprised to learn that Space Age technology designed to protect the astronauts from food poisoning has slowly become the safety standard for the food industry in the U.S. and abroad. Dubbed the Hazard Analysis and Critical Control Point (HACCP) system, this NASA spinoff has been called "the most revolutionary institutional innovation to ensure food safety of the twentieth century."[1]

For more than 30 years, canners who process low-acid foods have relied upon the risk prevention system developed by NASA to safeguard their products. More recently, HACCP regulations have been implemented by the U.S. Food and Drug Administration (FDA) to maintain the integrity of seafood and juice in the United States. The U.S. Department of Agriculture (USDA) also relies on HACCP systems in the nation's meat and poultry plants and slaughterhouses. There is, however, some disagreement over whether some of the more recent HACCP systems put in place by these regulatory agencies truly reflect the principles of an HACCP plan as outlined by food safety experts.

In nearly all cases, a series of food crises forced the regulatory agencies and industries to implement HACCP. In the 1970s, two well-publicized incidents and a growing consumer movement compelled industry and its trade representatives to adopt and lobby for the implementation of a preventive and comprehensive safety plan. The first occurrence happened in the spring of 1971.

1. John Spriggs and Grant Isaac, *Food Safety and International Competitiveness: The Case of Beef* (New York: CABI Publishing, 2001), p. 11.

Dr. Howard E. Bauman

A woman from Connecticut found glass in her baby's cereal. Soon after, Americans awoke to the news, hearing: "Good morning America, there's glass in your baby food." Pillsbury Company's farina, a creamy wheat cereal for infants, had been contaminated when shards of glass fell into a storage bin at one of Pillsbury's plants, forcing the company to recall the cereal. Upon hearing the news, Robert J. Keith, chief executive officer of Pillsbury, called Dr. Howard E. Bauman, a microbiologist and one of the company's research directors, into his office.[2]

Keith had worked for Pillsbury for more than 30 years and made his way up the corporate ladder, becoming CEO and chairman of the Board in 1967. During the five years he served in this position, he championed many popular causes, one of which included the growing consumer movement. Led by advocate Ralph Nader, consumers increasingly demanded safe food. Keith, sympathetic to such demands, told Bauman this incident would not happen again. Customers needed to know that the company's products were safe.[3]

Publicly, Pillsbury comforted customers by announcing a "considerable change" in the company's manufacturing processes, but this was not a PR campaign designed to halt fading consumer confidence.[4] Significant changes were underway at Pillsbury. In response to the recall, Keith pushed Pillsbury to implement a secure product safety system to minimize the likelihood of another recall of the company's food products.[5] For his part, Bauman saw to it that no food would be recalled under his watch. He planned to implement procedures he had helped develop years earlier while working with NASA, an idea he later pursued with HACCP.

Bauman began working at Pillsbury in 1953, when he completed his doctoral degree at the University of Wisconsin. He started out as head of research in the bacteriology section at Pillsbury and later assisted NASA, the U.S. Air Force Space

2. Dr. William H. Sperber worked with Dr. Bauman at Pillsbury, and he and his colleagues recall hearing this anecdote from Bauman. Dr. William H. Sperber, telephone conversation with author, 21 June 2006.

3. William J. Powell, *Pillsbury's Best: A Company History from 1869* (Minneapolis: The Pillsbury Company, 1985), pp. 190–191; Pillsbury Company, *Annual Report for the Year Ended 1973* (Minneapolis: The Pillsbury Company, 1973), p. 1; Sperber, telephone conversation, 21 June 2006.

4. "Pillsbury Recalls Cereal; Boxes May Contain Glass," *The New York Times*, 24 March 1971; Carole Shifrin, "Warning on Farina Cereal," *The Washington Post-Times Herald*, 25 March 1971.

5. Powell, *Pillsbury's Best,* p. 190.

Laboratory Project Group, and the U.S. Army Natick Laboratories with the food systems for the human spaceflight programs.[6]

Some of the other key individuals involved with the development and testing of the early space food systems included Herbert A. Hollender, Mary V. Klicka, and Hamed El-Bisi of the U.S. Army Natick Laboratories. Paul A. Lachance of NASA's Manned Spacecraft Center in Houston, Texas, rounded out the group.

Pillsbury became involved in the space program in 1959 when the Quartermaster Food and Container Institute of the United States Armed Forces (later called the U.S. Army Natick Laboratories) phoned Bauman and asked for Pillsbury's assistance. Would the Pillsbury Company be interested in producing space food? After some discussion, the company accepted and began working on cube-sized foods for the flight crews.[7]

Concerned about safety, NASA engineers specified that the food could not crumble, thereby floating into instrument panels or contaminating the capsule's atmosphere. To meet the outlined specifications, food technologists at Pillsbury developed a compressed food bar with an edible coating to prevent the food from breaking apart. In addition to processing food that would not damage the capsule's electronics, the food also had to be safe for the astronauts to consume.

Almost immediately food scientists and microbiologists determined that the assurance of food safety was a problem. Bauman recalled that it was nearly impossible for companies to guarantee that the food manufactured for the astronauts was uncontaminated. "We quickly found by using standard methods of quality control there was absolutely no way we could be assured there wouldn't be a problem," he said.[8] To determine food safety for the flight crews, manufacturers had to test a large percentage of their finished products, which involved a great deal of expense and left little for the flights.[9]

A survey conducted among experts in the field indicated there was no single standard quality control program for the food industry. Control programs were numerous and varied widely, according to Bauman: "Our surveys indicated that there were about as many variations of control progammes as there were quality control managers or Government inspectors."[10] Thus, there was no program already in place that could readily be used to provide a 100 percent guarantee of food safety.

6. Wolfgang Saxon, "Howard Bauman, 76, Expert Who Kept Food Safe in Space," *The New York Times*, 12 August 2001.

7. Howard E. Bauman, "The Origin of the HACCP System and Subsequent Evolution," *Food Science and Technology Today* 8, no. 2 (June 1994): p. 67.

8. "A Dividend in Food Safety," [NASA] *Spinoff,* (1991): p. 52.

9. Bauman, "The Origin of the HACCP System," p. 67; Howard Bauman, "HACCP: Concept, Development, and Application," *Food Technology* 44, no. 5 (May 1990): p. 156.

10. Bauman, "The Origin of the HACCP System," p. 68.

Paul Lachance

While Pillsbury was dealing with issues of food contamination, Paul Lachance completed a tour of duty with the U.S. Air Force Aeromedical Research Laboratories at Wright-Patterson Air Force Base in Dayton, Ohio. He was well aware of the issues concerning astronaut food as the Air Force laboratory provided support for the preflight feeding of the Mercury astronauts. Given his experience with Project Mercury, NASA recruited him and offered him the position of Flight Food and Nutrition Coordinator at the Manned Spacecraft Center in Houston.[11]

When Lachance arrived in September 1963, he began evaluating the Gemini and Apollo food systems, which were not very far along in development. Food safety for astronauts became an overriding concern for Lachance, who did not want a late night telephone call from Charles A. Berry "who was the Chief Medical Officer of NASA, telling me that his astronaut or astronauts were sick and had stomach problems and were having a hard time holding things down." Lachance also wanted to avoid putting the crews in jeopardy, and he began thinking about the potential microbiological, physical, and chemical dangers space foods might pose. Microbiological hazards became an overriding concern after NASA found that many of the ingredients they purchased were contaminated with viral or bacterial pathogens. There had to be some way to minimize or eliminate these hazards, Lachance explained.[12]

But no one was sure how to conduct a thorough hazard analysis, Bauman recalled. Eventually a suitable model, called the "modes of failure," was located, adopted, and utilized. Microbiologists began examining each food item and analyzed the potential areas of concern during the manufacturing process. Armed with this information, scientists then scoured publications to determine ingredients that were potentially dangerous—possibly containing viral or bacterial pathogens, heavy metals, other hazardous chemicals, or physical hazards. A list of hazards was then compiled.[13]

11. Paul A. Lachance interview, Houston, TX, 4 May 2006, JSC Oral History Project, JSC History Collection, University of Houston-Clear Lake.

12. Ibid.

13. Natick used "modes of failure" to analyze medical supplies. Bauman, "The Origin of the HACCP System," p. 68; Bauman, "HACCP," p. 156.

For their part, the Natick Labs established the microbiological standards for food that would be flown on piloted missions.[14] Requirements were stringent because scientific research had indicated that stress might weaken an astronaut's ability to fight infection. Even the smallest amount of a relatively harmless microorganism on Earth could potentially cause an astronaut in orbit to become ill. Thus, microbiologist Hamed El-Bisi of the Natick Labs concluded, "All possible measures must thus be taken to eliminate all pathogens and to minimize the microbial load in all food intake." He placed the total aerobic plate count at less than 10,000 per gram, meaning that the food was more likely to be safe for consumption by flight crews.[15]

This was a substantial change for the food manufacturers contracted to develop the Gemini food system. Previously, food processors had not measured pathogens unless they encountered bouts of food poisoning. By contrast, a hazard analysis required contractors to conduct pre- and in-process microbiology tests of food ingredients to ensure the health of the astronauts. Manufacturers had to assure NASA that their foods conformed to the microbiological standards outlined by Natick Laboratories. Food manufacturing conditions were strict; there were rigid temperature and humidity controls. Some foods were even processed in clean rooms, similar to the environment in which McDonnell Aircraft Corporation built the Gemini spacecraft.[16] If the food producers did not meet the microbiological standards, food technologists discarded the food.[17]

Bauman, who was assigned to the Gemini and Apollo Programs, was well suited for the position of ensuring the microbiological safety of astronaut food. Dr. Lachance recalled, Bauman was a microbiologist, " . . . and so he really knew his microbiology. So he was an ideal person, in some ways, to develop a laboratory where microbiology had to be paid attention to."[18]

As work on the Gemini program proceeded, Lachance turned his attention to the Apollo food system. The Apollo Spacecraft Program Office (ASPO) required

14. Robert A. Nanz, Edward L. Michel, and Paul A. Lachance, "Evolution of Space Feeding Concepts During the Mercury and Gemini Space Programs," *Food Technology* 21 (December 1967): p. 53; Space Food Systems Contract NAS 9-9032 Final Report, December 1970, Space Food Systems: Mercury Through Apollo (December 1970), Rita Rapp Files, Center Series, JSC History Collection, University of Houston-Clear Lake.

15. The microbiological standards were established in 1964. Hamed M. El-Bisi, "Microbiological Requirements of Space Food Prototypes," *Research and Development Associates for Military Food and Packaging Systems, Inc.* 17 (1965): pp. 55, 57; Charles T. Bourland interview, Houston, TX, 7 April 2006, JSC Oral History Project, JSC History Collection, University of Houston-Clear Lake; Edmund M. Powers, et al., "Bacteriology of Dehydrated Space Foods," *Applied Microbiology* 22, no. 3 (September 1971): p. 441.

16. Lachance interview, 4 May 2006.

17. Space Food Systems Contract NAS 9-9032 Final Report; Powers, "Bacteriology of Dehydrated Space Foods," p. 444.

18. Lachance interview, 4 May 2006.

its contractors to comply with certain reliability standards. Lachance had previously implemented reliability requirements for the Gemini food system but the ASPO required all contractors to develop prediction models for their systems to determine "critical failure areas" and then eliminate those hazards from the system.[19] Food contractors were not exempt from this requirement and had to sketch out their critical control points—places in the manufacturing process where the system could break down and put the hardware at risk.

Writing these blueprints forced Pillsbury to think logically about the steps in their process and identify critical control points. As the Apollo program matured, Pillsbury continued to revise the list of critical control points as they went along. Bauman explained what they learned along the way: "[A]s we worked along in this system, we found certain critical control points like telephones in the room. They are a good source of bacteria, unless you sterilize the receiver. That's something that you really don't always think of."[20]

Even though NASA required its food contractors to identify critical control points, NASA also determined them. In the specifications for most Apollo foods, NASA located 17 quality control stations in the production process; stations had acceptance and rejection standards for the inspectors, or in NASA-ese, "go" or "no go."[21]

Aside from monitoring the critical control points, contractors also had to keep records that documented the history of a food product. Records were kept from the moment the raw foods reached the plant. Logs indicated where the raw materials came from or, if the product had been processed, the name of the plant that produced the item and the names of people who worked in the manufacturing of that item. Strict recordkeeping allowed product tracking. "We knew the latitude and longitude where the salmon used in the salmon loaf were caught," Bauman joked.[22]

As a result of his NASA experience, Bauman became one of the biggest proponents of the HACCP concept, which was introduced to the food industry at the first National Conference on Food Protection in April 1971, just a few days after Pillsbury recalled packages of its farina cereal. The conference, sponsored by the American Public Health Association, opened on April 4 in Denver, Colorado. The main purpose of the conference was "to develop a comprehensive, integrated attack on the problem of microbial contamination of foods."[23]

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19. NASA, "Reliability Program Provisions for Space System Contractors," NPC 250-1 (Washington, DC: U.S. Government Printing Office, 1963), pp. 3-1, 3-2; Lachance interview, 4 May 2006.

20. The Pillsbury Company, Research and Development Department, *Development of a Food Quality Assurance Program and the Training of FDA Personnel in Hazard Analysis Techniques* (Minneapolis: The Pillsbury Company, 1973), p. 507.

21. Malcolm C. Smith, et al., "Apollo Experience Report—Food Systems" NASA TN D-7720 (Washington, DC: NASA, 1974), p. 9.

22. Bauman, "The Origin of HACCP," p. 68.

23. National Conference on Food Protection, *Proceedings* (Washington, DC: FDA, 1972), p. III.

Bauman served as vice chairman of Panel Number Two, which focused on the prevention of contamination of commercially processed foods. Other panel members included L. Atkin of Arthur D. Little, Inc., James J. Jezeski from Montana State University, and John H. Silliker of Silliker Laboratories, Inc., a food testing laboratory.[24] Convinced of the benefits of HACCP, Bauman encouraged his colleagues to consider the system as a plausible option for the food industry as a whole. The idea, however, was not immediately embraced, and a second incident occurred in the summer of 1971.

On a sweltering June night, Grace Cochran cracked open a can of Bon Vivant's vichyssoise (cold potato soup) for dinner. Samuel, her husband, ate a bite or two but then stopped, noting that the soup tasted spoiled. Grace had a spoonful and agreed. The next morning while driving to work in Manhattan, Samuel's vision began to blur. The condition continued to worsen, and a few hours after arriving at work he scheduled an appointment with doctors at the Eye Institute of the Columbia Presbyterian Medical Center. When he walked into the Center, Samuel's condition had deteriorated and doctors directed him to his personal physician. By the time he arrived at the hospital and met with his doctor, he had difficulty talking, could not turn his eyes left and right, could not swallow, and when he held his arms straight in front of his body, they shook. By 11 p.m., less than 8 hours after being admitted to the hospital, Samuel died.

A few hours later, Grace became ill. Dr. Henry P. Colmore, the internist who had treated her husband, visited Grace at her home. She told the doctor, "I'm doing just like Sam did. You don't suppose it was that soup we had last night? It tasted so bad we couldn't finish it." On the advice of Dr. Colmore, Grace's sons located the soup can while Colmore arranged for Grace to go to the hospital. Colmore was certain that Grace was suffering from botulism poisoning and that her husband had died from botulism. As a result of his findings, he notified the Westchester County Health Department.[25]

His phone call began a series of events leading to a national recall of Bon Vivant soups. Fearing a public health epidemic, Jack Goldman, county health commissioner, concluded that the department had to document the case. They needed the soup's lot number from the recovered can, but they needed additional evidence and found it. Cans of soup on the shelves at the local grocery store, bearing the same lot number, V-141/USA-71, were bulging. Armed with this information, Goldman contacted the state health department and the FDA, relaying the knowledge he had gathered. Eventually recalls for all Bon Vivant soups and other products made by the same manufacturer were issued and the factory shut down.[26]

24. Ibid., pp. 56–83.

25. Boyce Rensberger, "Grim Detective Case: Search for Vichyssoise," *The New York Times*, 18 July 1971.

26. Ibid; Nancy L. Ross, "Tracking Down the Soup Can Killer," *The Washington Post-Times Herald*, 18 July 1971.

This outbreak of botulism cast doubt over food safety in the U.S. and whether the FDA could protect citizens from contaminated food. Doubt had surfaced many times before this incident. In 1968 and 1969, for example, a Ralph Nader summer study group issued critical reports about the agency. In 1970, James S. Turner, the project director, revised the reports and published *The Chemical Feast: The Ralph Nader Study Group Report on Food Protection and the Food and Drug Administration*. In a chapter about the food industry, the bestseller detailed the FDA's friendship with food conglomerates and called upon the FDA to "enforce the law" rather than apologize on behalf of food processors who placed profits over consumer safety. "It is time the FDA set about *its* assigned task of insuring [*sic*] that profits made by the food industry are not the result of fraud, deception, adulteration, or misbranding."[27]

Employees of the FDA recognized the agency had problems. In July 1969, the FDA released the "Kinslow Report," commissioned by FDA Commissioner Dr. Herbert L. Ley, Jr. The study concluded, "The American public's principal consumer protection is provided by the Food and Drug Administration, and we are currently not equipped to cope with the challenge." In total, the panel submitted 45 recommendations to the Commissioner. Ley did not have time to implement any suggestions. In an attempt to overhaul the agency, Robert H. Finch, the Secretary of Health, Education, and Welfare, named Dr. Charles C. Edwards to the position of FDA Commissioner in December.[28]

After being removed from his post, Ley warned the public about the FDA's inability to safeguard consumers. People were being misled, he believed. "The thing that bugs me is that the people think the FDA is protecting them—it isn't. What the FDA is doing and what the public thinks it's doing are as different as night and day," he said. The agency, in his opinion, did not have the motivation to protect consumers, faced budget shortfalls, and lacked support from the Department of Health, Education, and Welfare.[29]

A year and a half later, when Samuel Cochran died from botulism and his wife suffered the ill effects of the disease, the FDA, its leaders, and food inspection processes continued to be under the microscope. Newspapers reported that the FDA had not inspected the Bon Vivant plant for four years. The last inspection took place in May 1967. Reporters asked about the lack of inspections and were told that workforce shortages often resulted in infrequent plant inspections. In some cases, the FDA had not inspected certain food plants for periods of up to 10 years.[30]

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27. James S. Turner, *The Chemical Feast* (New York: Grossman Publishers, 1970), pp. 85–86, 106.

28. Richard D. Lyons, "F.D.A. Shake-Up Will Start with Naming of New Chief," *The New York Times*, 10 December 1969; "Trouble Over Drugs on the Market," *The New York Times*, 4 January 1970; Andrew Hamilton, "FDA: New Pressures, Old Habits Bring a Change at the Top," *Science* (16 January 1970): pp. 268–270.

29. Richard D. Lyons, "Ousted F.D.A. Chief Charges 'Pressure' from Drug Industry," *The New York Times*, 31 December 1969.

30. Grace Lichtenstein, "Bon Vivant's Soup Plant Not Inspected for 4 Years," *The New York Times*, 21 July 1971.

Later that summer, as the recall of Bon Vivant soups was underway, another soup manufacturer—Campbell's—was recalling a batch of contaminated chicken vegetable soup. Fearing a public outcry, the company tried to quietly recall the canned soup. Testing later indicated that a few cans contained botulinum toxin.[31]

Later that summer, a Congressional investigation of the failure of federal food inspections began. When asked how the FDA was able to protect consumers from food poisoning, FDA Commissioner Edwards admitted that the agency's 250 food inspectors were overextended and the agency was short of funds. "We are daily falling farther and farther behind in our routine inspection activities," he said. Generally the FDA inspected plants once every six years. To inspect plants more frequently and bring them back to normal levels, the FDA needed to hire 1,500 inspectors and have its inspection budget raised from $18 million to $85 million a year. The Bon Vivant investigation had swamped the already overburdened FDA, and the FDA canceled more than 2,000 plant inspections in 1971.[32]

The Bon Vivant case continued to make headlines that fall. A government inspection of the Bon Vivant plant in Newark, New Jersey, indicated that the plant neglected food safety. Two problems in particular stood out: the company regularly undercooked its canned products and kept incomplete records. A government inspector summed up the review by saying, "[N]one [of the firm's products] are considered . . . to be safe for consumption by man or animal." For example, non-soup products suffered from poor quality control, as investigators found that more than half of all spaghetti sauce cans were defective—swollen, leaking, or had imperfect seams.[33]

Records indicate that Bon Vivant knew they had canning problems before this incident. As early as 1959, the corporation was aware of sealing problems, which led to leaking cans and defective seams. In 1962, the American Can Company warned Bon Vivant that the length of time that the company cooked batches of soups and sauces was insufficient.[34]

Newspapers continued to run stories about botulism as other cases became known. For the third time in 1971, the FDA issued a warning about botulism in canned foods when they learned that a batch of Stokley-Van Camp canned green beans might have contained the deadly toxin. The consequences were less deadly than the Bon Vivant case. An 8-year-old boy and his father, who ate beans from a swollen can, developed no symptoms but when the Centers for Disease Control and Prevention (CDC) injected mice with liquid from the can, they died.[35]

31. Richard D. Lyons, "Campbell Was Quietly Recalling Contaminated Soup Before It Learned of Botulin," *The New York Times*, 24 August 1971.

32. House Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, *FDA Oversight—Food Inspection—1971*, 92nd. Cong., 1st. sess., 1971, pp. 4, 11, 13.

33. Boyce Rensberger, "Federal Inquiry Charges Bon Vivant Soup Factory Had Wide Sanitary Violations and Faulty Records," *The New York Times*, 16 September 1971.

34. Ibid.

35. "Warning Is Issued on Stokley Beans," *The New York Times*, 30 October 1971.

The National Canners Association (NCA), fearful of a public backlash against canned foods as well as lack of consumer confidence in their products, petitioned the FDA for more government regulation to prevent the spread of botulism and other food-borne illnesses. Although only four botulism-related deaths had been linked to commercially canned food since 1925, the NCA hoped that by taking such action they could circumvent any negative press. Dr. Ira I. Somers, the research director for the NCA, explained, "We just don't think the canning industry can tolerate any more bad publicity. From a statistical standpoint our record is good but we want to tighten every screw we can."[36] By pushing for additional regulations, the NCA hoped to prove to consumers that they were committed to food safety practices.

The FDA published the NCA proposal, which reflected many of the principles of HACCP, in the *Federal Register* in November 1971. In the proposal, all canners manufacturing low-acid canned foods had to register with the FDA, listing the type of low-acid canned food processed at the plant. In addition, food processors would have to explain their processes as well as the equipment they employed in the manufacturing of such food. Other requirements included coding for containers, recordkeeping requirements, and training for retort operators and can seam inspectors. If companies failed to follow the outlined requirements, the FDA could invoke emergency permit controls whereby the cannery could not distribute its products until the owner had met specific conditions listed in the permit. Industry had 60 days to respond.[37]

Not all food processors agreed with the steps taken by the NCA and some challenged the association's actions. The American Shrimp Canners Association, for example, asked the NCA to withdraw its proposal. In response to their request, the NCA's Executive Vice President J. E. Countryman explained that their idea, while not a panacea, was "a significant constructive step toward providing increased safeguards in the processing of canned foods," and he added, "There can be no question that the whole canning industry benefits if this proposal begins the renewal of the public's faith in the safety and integrity of canned foods. For this reason alone, NCA has no choice but to allow the proposal to go forward."[38]

A dark cloud continued to follow the food industry and the FDA in the spring of 1972. In April, the U.S. Government Accountability Office (GAO) issued a damning

36. "Canners Petition F.D.A. for Stiffer Regulation," *The New York Times*, 26 October 1971.

37. Edward Dunkelberger, "The Statutory Basis for the FDA's Food Safety Assurance Programs: From GMP, to Emergency Permit Control, to HACCP," *Food and Drug Law Journal* 50, no. 3 (1995): p. 365; *Federal Register*, 12 November 1971, General Subject Files (1938-1974), FDA Records, Record Group 88, National Archives II, College Park, MD [henceforth: RG 88, Archives II]; House Committee, FDA *Oversight,* pp. 453–456.

38. J. E. Countryman to H. R. Robinson, 23 December 1971, General Subject Files (1938-1974), FDA Records, RG 88, Archives II.

report about unsanitary conditions in food manufacturing plants. The GAO's study of 97 plants found that standards of cleanliness in food plants had deteriorated from 1969 to 1972. Even worse, the "FDA did not know how extensive these insanitary conditions were and therefore could not provide the assurance of consumer protection required by the law."[39] To alleviate such conditions, the FDA had to take action.

The agency, which had provided some funds for the first National Conference on Food Protection, had learned of HACCP at the meeting. Searching for a "better, more comprehensive food protection [program] for the consuming public," the FDA asked the Pillsbury Company to provide HACCP training for its supervisors and investigators. In September of 1972, 16 inspectors attended the first class offered in Gull Lake, Minnesota.[40] Pillsbury's three-week course included 11 days of lectures and 10 days of field work in Minnesota canning plants.[41] Upon completing the training, the inspectors returned to their posts, and later the following year the FDA established permanent low-acid canned food regulations. This represented the first regulatory use of HACCP in the food industry.

The implementation of HACCP regulations had a tremendous impact on canners of low-acid foods and their quality control programs. Joseph P. Hile, Executive Director of Regional Operations for the FDA, explained, "Some firms had no real quality control program until after FDA made its HACCP inspection and identified the crucial needs." Other food plants, Hile stated, "ceased operations as a result of these inspections until major equipment improvements are made and meaningful plant quality control procedures instituted."[42]

This was the case for Western Natural Growers, Inc., of Ulysses, Kansas. In the fall of 1973, an inspector reported that "Processing procedures, equipment and the firm's general knowledge of retort operations are so grossly inadequate that the production of low acid canned foods from this firm could represent a threat to consumer safety." The plant's retort operators had not attended any FDA- or NCA-approved schools and the plant failed to maintain any processing and production records with the exception of temperature recording charts. Following the inspection, the FDA Bureau of Foods requested that the plant cease operation until the agency believed that they understood and could comply with low-acid canned food regulations. On November 1, the plant was voluntarily shut down. Notes from a December inspection indicate that conditions

39. U.S. Government Accountability Office, *Dimensions of Insanitary Conditions in the Food Manufacturing Industry; Report to the Congress [on the] Food and Drug Administration, Department of Health, Education, and Welfare* (Washington, DC: GAO, 1972), p. 2.

40. Pillsbury Company, *Development of a Food Quality Assurance Program,* iii, 733; F. Leo Kauffman, "How FDA Uses HACCP," *Food Technology* 28, no. 9 (September 1974): p. 51.

41. Sperber, telephone conversation, 21 June 2006.

42. Joseph P. Hile, "HACCP—A New Approach to FDA Inspections," *Food Product Development* 8, no. 1 (February 1974): p. 52.

at Western Natural Growers, Inc., had substantially improved; retort operators, for instance, were scheduled to attend an FDA/NCA school at the University of Arkansas and were maintaining processing and production records.[43] Naturally, these equipment and operation changes resulted in some increased costs for the company.

Other smaller canners were not as fortunate as the Western Natural Growers. Some went out of business as a result of the adoption of these regulations. The rules also had significant impact upon the canned seafood industry, where many smaller plants closed.[44]

Aside from the impact on quality assurance in canneries, plant inspections also changed as a result of the FDA's use of the HACCP concept. Hile, who had at one time worked as an inspector for the agency, recalled that the inspections previously conducted by the FDA varied; some were brief while others were in-depth, and the length of inspections was determined at the local level. HACCP guidelines, by contrast, laid out the details by which all plants across the country would be inspected by the agency and, in general, HACCP inspections followed a nationwide, uniform model.[45]

Another key difference between traditional factory inspections and the HACCP inspections was the approach taken by the investigator. Customarily, canning plant inspections were limited in scope by the time the inspector spent at factory. HACCP inspections, by contrast, entailed the examination of records, thereby giving inspectors a broader picture of how the plant operated over the course of the year, not just the hours the investigator spent at the plant.[46]

FDA records indicate that canning safety programs improved over a period of four years from 1973 to 1977. During this time, FDA inspectors found fewer factories processing food that had either major or critical deviations from low-acid canned food regulations. Most companies complied with FDA requirements and approximately 10,000 people attended about 100 FDA-approved canning courses.[47]

In 1980 the FDA commissioned a study to determine the total costs of the low-acid canned food regulations on plants. Arthur D. Little, Inc., of Cambridge, Massachusetts, conducted the study, and more than 800 plants participated in the review. Arthur D. Little calculated that the industry spent $85 million to comply with the regulations, with an average cost of $102,000 per factory. Compared to

43. Establishment Inspection Endorsement, 18–19 September 1973, General Subject Files (1938–1974), FDA Records, RG 88, Archives II; Establishment Inspection Endorsement, 9 November 1973, General Subject Files (1938–1974), FDA Records, RG 88, Archives II; HACCP-EIR Evaluation Critical Factors-Potential Hazard to Public Health, 19 December 1973, General Subject Files (1938–1974), FDA Records, RG 88, Archives II.

44. U.S. Food and Drug Administration, *Total Industry Cost of Compliance with Low-Acid Canned Food Regulation Report to the Food and Drug Administration*, prepared by Arthur D. Little, Inc., 21 November 1980 (Rockville, MD: U.S. Food and Drug Administration, Office of Planning and Evaluation) p. IV-6.

45. Hile, "HACCP," p. 50.

46. Ibid.

47. "Canning Safety Practices Improve," *FDA Consumer* 13, no. 1 (February 1979): p. 23.

smaller facilities, larger plants tended to spend less on compliance. Overall, however, the burdens of compliance were insignificant, amounting to less than 1 percent of the low-acid canned food's shipment value.[48]

By 1974 Pillsbury had achieved its objective of implementing a new product safety standard at its facilities. The company's annual report boasted that the HACCP system was in use in the Pillsbury food plants and in its Burger King restaurants. The concept employed three principles: 1) conduct a hazard analysis, 2) determine critical control points, and 3) establish monitoring procedures.[49] Soon the concept would be employed in its more recent acquisitions, the Souverain wineries and Wilton plants.[50]

The attainment of Keith's goal represented a significant accomplishment for the company and a distinct turning point in the history of food safety. Instead of relying solely on end-product testing to ensure the safety of their products, Pillsbury had implemented a total safety system which affected not only their quality assurance programs but all phases of production. Bauman contrasted the old and new safety systems in an FDA training seminar. Under the old system, product development, testing, and marketing were quick and relatively easy; all of the Pillsbury offices conducted their work in relative isolation. By contrast, the total safety system integrated the research and development work to involve all employees. Where the company once viewed quality control as a final, isolated step, Pillsbury now viewed all stages of development as interrelated. Conducting a hazard analysis and identifying critical control points involved not only the quality control employees but individuals from all parts of the company—engineers, scientists, marketers, and attorneys. In addition, the company organized a number of offices to ensure product safety, such as the Product Systems Safety Office which verified that all new products had undergone an HACCP assessment. Aside from processing modifications, the culture of the company's middle management also changed.[51]

For his part, Bauman kept his word to the CEO of Pillsbury. Under his watch, the company did not have a major recall.[52] Pillsbury was pleased with their implementation of HACCP, saying, "There have been more than 130 food safety-related recalls of product from the marketplace from 1983 to 1991. None were Pillsbury products. HACCP works!"[53]

48. FDA, *Total Industry Cost of Compliance*, pp. I-4, I-5, I-6.

49. William H. Sperber, "HACCP and Transparency," *Food Control* 16 (2005): p. 506.

50. The Pillsbury Company, *Annual Report for the Year Ended 1974* (Minneapolis: The Pillsbury Company, 1974), p. 14.

51. Pillsbury Company, *Development of a Food Quality Assurance Program*, pp. 315–328, 514.

52. Bauman, "The Origin of the HACCP System," p. 69.

53. "A Dividend in Food Safety," p. 53.

Even with Pillsbury's successful implementation of an HACCP program in the early 1970s, interest in the system dwindled until the 1980s, when HACCP began to be revisited. In 1980, at the request of the National Marine Fisheries Service, the USDA, the FDA, the U.S. Army Natick Research and Development Center, and the National Research Council's Food and Nutrition Board Subcommittee on Microbiological Criteria formulated microbiological standards for food and drafted a plan of action for regulatory agencies to implement an HACCP system. Two members of the committee, James J. Jezeski and John H. Silliker, had previously served as panel members at the first National Conference on Food Protection where the idea had been unveiled. The committee's final report made mention of the historic event, noting that HACCP inspections provided a better approach than traditional inspections. As an example, the committee noted that the HACCP system helped the low-acid canned food industry control microbiological hazards. The group concluded that the HACCP concept was a valuable approach to securing the food system, and members urged regulatory agencies and the food industry to adopt the system.[54]

The Food and Safety Inspection Service (FSIS, a USDA agency) made a similar request of the Food and Nutrition Board of the National Research Council in 1983. They asked the board, which coincidentally included Norman D. Heidelbaugh, a veterinarian who had worked on the food systems at NASA, to evaluate the agency's meat and poultry inspection system. Upon completing its study, the board recommended that FSIS adopt HACCP principles in slaughterhouses and processing plants; in addition, the board encouraged the agency to train inspectors in the HACCP concept.[55] Together, these two reports rekindled widespread interest in HACCP in the U.S.

In response to the recommendations, the FSIS established the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in 1988. Cosponsored by the FDA, the CDC, the National Marine Fisheries Service (NMFS), and the Department of Defense Veterinary Service Activity, the committee provided an interagency look at microbiological standards for food. Bauman, who still worked at Pillsbury as vice president for science and regulatory affairs, served on the first NACMCF and remained on the committee until 1992. His colleague, William Sperber, joined in 1990.[56] In 1992, the committee recommended HACCP as an effective food protection system. A number of experts came out in favor of HACCP and another key report, "Cattle Inspection," encouraged the U.S. federal regulatory agencies to adopt HACCP-based systems.

54. National Research Council (U.S.) Food Protection Committee Subcommittee on Microbiological Criteria, *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients* (Washington, DC: National Academies Press, 1985), pp. 50–51, 308.

55. National Research Council Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program* (Washington, DC: National Academies Press, 1985), pp. 8, 134–136.

56. Sperber, telephone conversation, 21 June 2006.

Pressure to adopt HACCP systems also came from international governing bodies. In the summer of 1993, the Codex Alimentarius Commission (CAC), a joint program of the United Nation's World Health Organization and Food and Agriculture Organization, adopted *Guidelines for the Application of the Hazard Analysis Critical Control Point System*. But, in spite of the urging of experts, no change came about in the meat and poultry industry. [57]

The impetus came when hundreds of people fell sick and four children died after eating *E. coli*-contaminated hamburgers from a Jack in the Box fast food restaurant in the winter of 1993. The incident might have been avoided if the beef industry, food service establishments, or the USDA had implemented HACCP inspections. Eight years earlier, the National Research Council's Subcommittee on Microbiological Criteria had encouraged restaurants to adopt HACCP systems in their operations because research had overwhelmingly linked such establishments to most outbreaks of food-borne illness.[58]

The deaths of several small children from this incident led many to question the safety of the nation's meat. In a televised PBS *Frontline* interview, Carol Tucker Foreman, director of the Food Policy Institute at the Consumer Federation of America, explained how the deaths altered America's view of safety and the role of the USDA in preventing food crises. The *E. coli* outbreak indicated that the USDA inspections had not kept pace with America's increasing dependence on prepared and processed foods. "[I]t exposed the fact that the meat inspection system has not changed a bit since 1906. We were using methods that were essentially a century old in an industry that had changed radically," she said.[59] For instance, USDA inspectors continued to use the "sniff and poke" method to determine whether carcasses were safe for consumption, rather than rely on microbiological testing.

As Jack in the Box saw its sales slip, the fast food giant hired food scientist David M. Theno to prevent another disaster. Theno was a proponent of the HACCP system and he had previously used such methods to eliminate nearly all traces of *Salmonella* in the poultry at Foster Farms, the largest poultry producer in the western U.S. After reviewing Jack in the Box records, he laid out a plan to implement an HACCP program in the chain's restaurants. Jack in the Box was the first fast food chain to implement the system and require its suppliers to implement such plans. The standards were strict. For instance, meatpackers selling to Jack in the Box had to conduct microbiological tests on their beef every 15 minutes during processing, and managers were required to attend food safety courses. The implementation of the HACCP system increased beef costs by a mere penny per pound.[60]

57. Instead, FSIS conducted an HACCP study to determine how to implement HACCP procedures in the meat and poultry industry. "A Dividend in Food Safety," p. 54.

58. National Research Council, *An Evaluation of the Role of Microbiological Criteria*, pp. 314–315, 326.

59. PBS, *Frontline: Modern Meat, http://www.pbs.org/wgbh/pages/frontline/shows/meat/interviews/foreman.html* (accessed 3 August 2006).

60. Eric Schlosser, *Fast Food Nation: The Dark Side of the All-American Meal* (New York: Perennial, 2002), pp. 208–210.

The Jack in the Box incident proved that USDA inspection methods were antiquated, as inspectors could not necessarily see microbiological hazards. In response, FSIS issued a proposed a Pathogen Reduction/HACCP (PR/HACCP) rule in the *Federal Register* in February 1995. The proposal had three parts: the first section required the meat and poultry industry to develop and implement sanitation standard operating procedures (steps taken to prevent food contamination); second, the agency aimed to reduce *Salmonella* in meat and poultry plants and proposed daily microbiological testing at slaughterhouses and at facilities grinding meat; and third, the proposal would require all meat packing plants, slaughterhouses, and food processors handling meat and poultry to adopt HACCP plans.[61] Industry had 120 days to comment. The proposal pleased those who hoped to modernize the inspection process. "It may not be *Star Trek the Next Generation*, but it gets the USDA out of the horse and buggy era," said Foreman.[62]

When the rule was finalized in 1996, the press touted the achievement as a landmark in food safety. In a Saturday morning radio address, President Bill Clinton proclaimed that the new rules strengthened regulations, protecting families and those most vulnerable to pathogens—children. Recalling the Jack in the Box incident, he said, "Parents should know that when they serve a chicken dinner, they are not putting their children at risk."[63]

Experts, however, disagreed with Clinton's assessment. William Sperber, a food safety expert now with Cargill, believed that this rule, known more commonly as the "Megareg," and the additional HACCP regulations passed by the FDA in 1997 and 2001 did not follow the principles of HACCP as outlined by the NACMCF and later by the CAC. As an example, Sperber explained that sometimes meatpacking plants failed to meet the *Salmonella* performance standards as outlined by the USDA regulation. The rule gave the USDA the authority to close the plant if a packer failed the *Salmonella* monitoring plan three times in a row. FSIS rarely employed such drastic measures, however. Instead, the USDA waited to conduct another round of samples that consumed several months, and the meatpacking plants continued shipping meat until the results came back. This process sometimes took two years to complete. Very rarely did FSIS proceed to close a plant. The hesitancy with which the agency took action is not reflected in the HACCP principles outlined by the NACMCF. "Several hallmarks of a valid HACCP plan are that monitoring procedures and corrective actions, insofar as possible, should be taken in real time, and should be as continuous as possible," Sperber noted.[64] In other words, the USDA failed to implement a true HACCP

61. *Federal Register*, 25 July 1996.

62. Marian Burros, "Sweeping Changes Proposed on Meat Safety," *The New York Times*, 1 February 1995.

63. Todd S. Purdum, "Meat Inspections Facing Overhaul, First in 90 Years," *The New York Times*, 7 July 1996.

64. Sperber, "HACCP and Transparency," p. 507.

system because the agency allowed certain meatpackers to ship inferior and potentially unsafe meat, and because it relied on product testing for *Salmonella* rather than more practical process controls.

Likewise, food inspectors voiced concern about the rule, which, they argued, put the public at greater risk for food-borne illness. The regulation had taken away their authority to check contaminated meat. Instead of visually examining carcasses, inspectors had to ensure that companies followed the HACCP system they had drawn up. The acronym, which had once outlined the steps to ensure food safety—Hazard Analysis and Critical Control Points—was now dubbed "Have a Cup of Coffee and Pray" by those inspectors opposed to the Megareg.[65]

In spite of the criticism leveled against the PR/HACCP regulation, the Economic Research Service (ERS) of the USDA linked the implementation of the rule to a 20 percent reduction in food-borne illness and lower medical costs.[66] Similar trends were noted by another federal agency: the CDC cited HACCP as one factor contributing to the decrease in the number of *Salmonella* infections over a five-year period.[67]

After further review, the costs of developing and implementing an HACCP plan were higher than previously assumed. FSIS had estimated that the costs of PR/HACCP would be relatively insignificant, about 0.12 cents per pound. The ERS found that the actual overhead was higher than anticipated, 0.4 cents a pound for poultry and 1.2 cents for beef. This amounted to a 1.1 percent increase for plant operators. For cattle slaughterhouses the rates were higher, about 5.5 percent of all costs.[68] Although costs have been higher than expected, this has not hindered the adoption of HACCP systems in the U.S. and abroad.

The emergence of new pathogens in foods, as well as consumer demands for safe food, has driven the use of HACCP in other nations. In Australia, for instance, an *E. coli* outbreak sickened more than 100 people and killed one child, forcing changes in food safety requirements. The passage of the Australian Standard for Hygienic Production of Meat for Human Consumption required plants to implement HACCP systems in their meatpacking plants.[69] Scotland required its butchers to employ HACCP

65. Schlosser, *Fast Food Nation*, p. 215.

66. Michael Ollinger and Valerie Mueller, *Managing for Safer Food: The Economics of Sanitation and Process Controls in Meat and Poultry Plants*, Agricultural Economic Report No. AER817 (April 2003): pp. vi, 59, *http://www.ers.usda.gov/publications/aer817/* (accessed 3 August 2006).

67. Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Foodborne Illness—Selected Sites, United States, 2001," *Morbidity and Mortality Weekly Report*, 19 April 2002, *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5115a3.htm* (accessed 3 August 2006).

68. Ollinger and Mueller, *Managing for Safer Food*, p. 58.

69. Spriggs and Isaac, *Food Safety and International Competitiveness*, pp. 111, 115.

procedures after 21 people died from eating tainted meat at a butcher shop.[70]

Throughout the past three decades, the widespread use of HACCP in the U.S. and abroad indicates the impact NASA has had on the food industry and food safety regulations. Originally implemented on a small scale for NASA's Gemini and Apollo astronauts, the HACCP system is essentially utilized worldwide by many multinational food conglomerates to ensure food safety for billions of consumers. In addition to the tremendous growth of the HACCP approach, many regulatory agencies require certain sectors of the industry to design and utilize systems in their processing plants that can be linked to the techniques first developed to comply with NASA food safety regulations.

Perhaps more important, HACCP has changed the manner in which food manufacturers and regulators look at the issue of food safety. Just 20 years ago many food manufacturers believed that the issues of food safety belong solely in the hands of quality control and quality assurance engineers in food processing plants. Today this is not the case. William Sperber explains this shift: "We now realize that some food safety practices can be applied at each step of the global food chain; from the growing of crops and the raising of animals, to the processing of these commodities, and through the production, distribution, and consumption of consumer food products."[71]

70. Food and Agriculture Organization of the United Nations (FAO), "Escherichia Coli 0157: H7 Outbreak in Scotland in 1996/97," FAO/WHO Global Forum of Food Safety Regulators, Marrakesh, Morocco, 28–30 January 2002, *http://www.fao.org/DOCREP/MEETING/004/X6925E.HTM* (accessed 3 August 2006).

71. William H. Sperber, "Opening Remarks," *Food Control* 14 (2003): p. 73.