Chapter 3

The Shift to a New Regulatory Paradigm

The public health community has known since the 1960s that foodborne bacteria, such as *Salmonella*, can cause human illness. This concern led the American Public Health Association (APHA) to file a lawsuit asking the court to declare *Salmonella* an adulterant and requiring that a warning label giving cooking instructions be affixed to the package. However, the Supreme Court in 1972 ruled against the suit, saying that APHA presented no evidence showing that *Salmonella* was any more likely to be present in poultry than in any other food product, and that it is common knowledge to cook meat and poultry adequately. However, FSIS and the general public became more cognizant of the virulence of pathogenic bacteria in the 1980s when a series of foodborne illness outbreaks gained prominent news coverage. The first one, an outbreak of *E. coli* 0157:H7, occurred in an Oregon McDonalds in 1982. The incident produced no fatalities, but a number of customers became ill with bloody stools and other symptoms. Just as publicity over that incident began to subside and experts began to feel the incident was unique, a second outbreak occurred in Michigan and other States. These events and several additional ones involving one roast beef and four ground beef incidents convinced the Centers for Disease Control and Prevention (CDC) that the outbreaks were meat related (Griffen and Tauxe, 1991).

Other pathogens also soon caught the public's attention. In 1988, the television program *60 Minutes* featured a segment on the health effects and sources of *Salmonella.* Although this naturally occurring organism is found in many raw and cooked products, the program focused on the poultry industry. The *60 Minutes* program brought the issue to the public's attention and precipitated consumer demands for change. In response, the poultry industry promoted the development and testing of counter current scalders, bird washes, chlorine rinses, and other pathogen-reducing technologies that significantly reduced *Listeria monocytogenes*, S*almonella*, and *Campylobacter* levels in chicken products (Waldroup et al., 1992). These and other newer technologies were then rapidly and voluntarily adopted by the industry. However, according to recent FSIS findings, *Salmonella* still is present on about 20 percent of all young chickens, and Mead et al. (1999) of the CDC estimated that *Salmonella* caused 1.3 million illnesses and 550 deaths in 1997. The Economic Research Service estimated the 1997 cost of *Salmonella* cases at about $2.4 billion (*www.ers.usda.gov*, January 2002). Cost estimates include lost wages and medical expenses. *Salmonella* poisoning comes from a variety of foods, including meat, poultry, and eggs, as well as from pet handling. The contribution from meat, poultry, and eggs is uncertain.

The potential health effects of other pathogens also gained notice. As reported by Farber and Peterkin (1991), *Listeria monocytogenes* caused the most deaths ever recorded for a foodborne illness in Chicago when 142 known cases resulted in 48 deaths in 1985. Roberts and Pinner (1990) estimated that *Listeria monocytogenes* caused 1,350 illnesses and 510 deaths nationwide in 1986, and Mead et al. (1999) estimated that the pathogen caused about 2,500 illnesses and 500 deaths in 1997. Evidence of the health effect of *Listeria monocytogenes* led FSIS to declare it an adulterant in cooked meat or poultry, assign it a zero tolerance, and begin testing for it in 1989 (Peter Perl, *Washington Post Magazine*, January 16, 2000).

Listeria monocytogenes, like *Salmonella*, is a commonly occurring bacteria that is killed in the cooking process. The bacteria finds hospitable surroundings on soft cheeses and other dairy products from unpasteurized milk, seafood, dry and semi-dry fermented sausages, deli meats and poultry, and other ready-to-eat dairy and meat and poultry products. However, if reintroduced onto the product from the environment after cooking or if the product is not thoroughly cooked, it can be deadly, particularly for fetal/newborns, elderly adults, and immuno-compromised people. A 1998 outbreak caused by the presence of *Listeria monocytogenes* in hot dogs and deli meats from a Sara Lee plant killed 15 people and sickened over 100.

Less well known as a source of foodborne illness is *Campylobacter*. Epidemiologists had trouble determin-

ing the public health consequences of this pathogen until the mid-1980s when scientists were first able to grow it in laboratories. Today, however, *Campylobacter* is recognized as the most common cause of foodborne illness. Mead et al. (1999) estimated that about 100 people died and 2.0 million people became sick due to *Campylobacter* infections in 1997.

Living in the intestine of the infected animal and spreading to the surface at slaughter, *Campylobacter* is extremely common in poultry. It contaminated about 80 percent of all poultry products at the retail level in 1991 (Skirrow and Blaser, 1992, p. 4), making consumption of it in undercooked poultry or through cross-contamination the most common way of contracting a sporadic *Campylobacter* infection (Tauxe, 1992, p. 12). People can also get *Campylobacter* from contaminated drinking water, unpasteurized milk, or raw or undercooked meat.

Large Outbreak of Foodborne Illnesses Focuses Public Attention on Food Safety

Public awareness of the threat to human health posed by pathogenic bacteria skyrocketed when an *E. coli* 0157:H7 poisoning seized public attention in January 1993. In this incident, 4 people died and more than 500 became sick, mainly in Washington, Idaho, and Nevada. After studying the epidemic, public health officials in Washington, DC, and at the CDC identified the consumption of hamburgers at Jack-in-the-Box fast-food restaurants as the source. In Washington State, where the largest outbreak occurred, the investigation suggested that Jack-in-the-Box employees cooked hamburgers below the State standard of 155 degrees Fahrenheit and in some instances below the 140 degrees Fahrenheit recommended by the Food and Drug Administration (*Federal Register* announcement, 1996).

Following the Jack-in-the-Box outbreak, FSIS began to take a new approach to its public health mission. Since pathogens are not visible to the human eye, the visual inspections that prevented diseased animal meat from entering the food supply proved to be of questionable effectiveness against unseen pathogens. So, FSIS began to focus more of its attention on pathogen testing and sanitation and process controls.

FSIS was particularly concerned about the presence of *E. coli* 0157:H7. It established a zero tolerance level in ground hamburger because fewer than 50 organisms are believed to be able to cause serious illness. To support this policy, FSIS began testing 5,000 1-ounce samples of raw hamburger per year for *E. coli* 0157:H7. These tests for *E. coli* 0157:H7 in raw meat and those for *Listeria monocytogenes* in cooked products cannot ensure that all meat is free of either pathogen, but the tests are intended to encourage firms to make stringent efforts to prevent pathogens of public health significance from being present and growing in their products.

The penalties for finding pathogens are severe. FSIS asks, but cannot mandate, the plant to recall its products and issues a press release. If the plant refuses to recall the products, FSIS can seize the product. Although these options are costly, it could also be very costly not to recall products. For example, if an outbreak were to occur and be traced back to the offending plant, then the plant's owner could face ruinous legal liability claims and the plant would risk a loss of reputation and could possibly be held liable for damages.

As a way to better control pathogens, FSIS began to seriously consider the use of a Hazard Analysis and Critical Control Point (HACCP) process control system in the early 1990s and began a pilot program with a limited number of plants to determine its effectiveness. This was not a new idea. Many restaurants, such as McDonalds and Jack-in-the-Box, required HACCP of their suppliers, and several meat and poultry firms, such as Excel, already used it in their plants (Ollinger, 1996). Indeed, Booz-Allen, in its 1977 report, had recommended the use of a quality control program with many of the elements of a HACCP program. Later, the National Academy of Sciences (1985, 1987, and 1991), the National Advisory Committee on Microbiological Criteria for Foods (1988), and the General Accounting Office (in a series of reports in the early 1990s) called for the use of HACCP systems in the meat industry.

The Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) rule, initially proposed by FSIS on February 3, 1995, incorporated many elements of the HACCP programs recommended by other organizations. It differed from the traditional inspection and control systems in that it considered the production process in its entirety and focused on prevention rather than merely on detection and adjustment. FSIS based its plan on these seven criteria: (1) assessing all hazards, (2) finding all critical control points, (3) setting critical limits for each critical control point (CCP), (4) developing procedures to monitor each

CCP, (5) determining corrective actions, (6) implementing a recordkeeping system, and (7) establishing verification procedures (Unnevehr and Jensen, 1996).[1] Besides having elements consistent with these criteria, FSIS proposed to hold plants responsible for failure to implement and maintain their HACCP systems.

Food Safety Under the Pathogen Reduction HACCP Rule

FSIS published the final PR/HACCP rule on July 25, 1996. The rule was phased in over a 3-year span starting in January 1998. The largest plants (more than 500 employees) had to comply by the end of January 1998, small plants (10-499 employees) had until January 1999, and very small plants (fewer than 10 employees or annual sales fewer than $2.5 million) had to conform by the end of January 2000. All plants had to have sanitation standard operating procedures (SSOPs) in place by January 1997, regardless of size.

The principal element of the rule was the development of a HACCP plan for each FSIS-defined product group that clearly established and controlled CCPs in the plant's production system. There were other important components, however. First, PR/HACCP required meat and poultry establishments to develop and implement written SSOPs. Second, it mandated that slaughter plants conduct generic *E. coli* microbial tests in order to verify that fecal contamination was under control. Finally, in order to verify that their HACCP systems were controlling pathogens, the PR/HACCP rule established *Salmonella* performance standards for slaughter and ground meat and poultry plants.

In conjunction with the PR/HACCP rule, FSIS eliminated several formerly necessary requirements. For example, FSIS no longer required prior approval for equipment installations or plant construction (*Federal Register*, 1996). Changes that did affect the HACCP plan or food safety, however, did require a revised HACCP plan.

The PR/HACCP rule requires plants to identify CCPs, take responsibility for implementation and control of their HACCP programs, maintain performance records, and adopt plans for action should processes get out of control. PR/HACCP also stipulates that each plant must complete a HACCP plan for each of its manufacturing processes (e.g., raw beef not ground). This plan contains a flow chart that notes all possible hazards for each step of the production process. Additionally, these plans include critical limits, monitoring procedures, corrective actions, recordkeeping methods, and verification procedures for each CCP.

[1] CCP refers to any part of the production process where food safety is at risk.

HACCP Programs Under PR/HACCP

The new PR/HACCP program shares similar characteristics and features with the TQC program that it superseded. PR/HACCP, like TQC, requires that plants take responsibility for implementation and control of food safety process control, maintain performance records, and adopt a plan for action in the event that a process gets out of control. TQC plants were also required to identify control points, while a HACCP plan calls for identification of critical control points. Additionally, FSIS inspectors ensure plant compliance by verifying written records and plant activities. PR/HACCP deviates from the TQC program in that TQC programs dealt with aspects of food quality not specific to food safety and were voluntary, while the HACCP programs required under PR/HACCP deal only with food safety and are mandatory. Hence, if a plant did not adhere to the requirements of the TQC, FSIS could cancel the plant's status as a TQC plant, causing the plant to revert back to the traditional inspection method, but the plant could continue meat or poultry production as long as FSIS found the product not to be adulterated. However, since PR/HACCP requires use of a HACCP program, a plant can be temporarily shut down for failing to adhere to its HACCP plan, regardless of whether FSIS found its products to be adulterated. The plant can resume operations as soon as it adheres to its HACCP plan.

Sanitation Procedures and HACCP Under PR/HACCP

FSIS has required plants to perform sanitation and process control tasks since Congress passed the Wholesome Meat Act (WMA) of 1967 and Wholesome Poultry Products Act (WPPA) of 1968. However, the PR/HACCP rule shifted legal responsibility for adhering to sanitation standard operating procedures (SSOPs) to the plant by requiring that a plant official with overall site authority accept responsibility for them. In their SSOPs, plants must: (a) identify operational and pre-operational procedures that, at a minimum, include the cleaning of all surfaces that contact meat or poultry; (b) identify individuals responsible for daily sanitation activities, and (c) maintain

records showing that the plant is adhering to their SSOPs. The main difference between these requirements, which were issued within a specific regulatory scheme alongside the HACCP requirements, and those under the WMA of 1967 and WPPA of 1968 is that plant personnel are now legally responsible for maintaining records and adhering to sanitation SSOPs.[2]

Salmonella and Generic *E. Coli* Testing Under PR/HACCP

The PR/HACCP rule included both pathogen testing requirements and the development and implementation of HACCP plans. Pathogen testing marked a sharp departure from previous practices by establishing tolerance levels for *Salmonella* and generic *E. coli* and then permitting plants to use any means available to meet the tolerance. Failure to meet the tolerance could result in a plant shutdown. HACCP plans under PR/HACCP were enforced in much the same way as existed for sanitation and process controls under WMA and WPPA. Under each program, plants have a set of tasks that they are required to perform and that FSIS verifies. The main difference is that under PR/HACCP, there are structures codified for both sanitation and food safety that previously were not as detailed.

FSIS enforcement actions changed to reflect the implementation of new pathogen performance standards. PR/HACCP required all slaughter plants to conduct microbial tests for generic *E. coli*, and all slaughter and ground meat plants to adhere to *Salmonella* standards. Slaughter plants conduct their own generic *E. coli* tests. The number of tests depends on production volume. For example, cattle slaughter plants have to take one sample per 300 carcasses, while broiler plants are required to take one sample per 22,000 birds. Plants failing to meet the generic *E. coli* standard must discover and correct the cause of the failure or face increased FSIS scrutiny of facilities, products, and plant compliance with their HACCP plan SSOPs. FSIS may also perform more product testing. If plant performance is deemed unsatisfactory, FSIS can remove its inspectors.

FSIS conducts *Salmonella* tests, uses the results as a measure of overall plant process control, and can deem a failure to meet the standard as one of the bases for declaring a product to be adulterated. The testing process takes a random selection approach that gives plants several chances to meet the standard before enforcement actions are taken. If a plant fails the first test, it must complete a second round of tests after it modifies its process. If the plant fails that round, then again, it must undergo another round of testing after it modifies its processes. Failure to pass on the third attempt constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan and will cause FSIS to suspend inspection services. The suspension remains in effect until the plant submits a detailed action plan to correct the HACCP plan and outlines the other measures taken by the plant to reduce the prevalence of pathogens.

It has been rare for plants to fail *Salmonella* compliance testing. Only about 100 out of the approximately 2,050 slaughter and grinding plants tested up to 1999 failed to pass the first test and only 22 of these 100 plants failed their first two tests. Failure to comply after two tests would have led to increased enforcement review, but 19 of these plants passed the third test and continued production. These 19 plants included 1 for ground turkey and 7 for ground beef, and 4 hog slaughter, 6 broiler slaughter, and 2 cow and bull slaughter plants. Supreme Beef and one other ground beef plant and one cow and bull slaughter plant failed three tests, and FSIS suspended them, meaning that plants retained the right to inspection services if the suspension was lifted.

The suspension of inspection services at Supreme Beef was quite controversial and prompted a lawsuit to overturn FSIS's right to suspend inspection services for failure to comply with the *Salmonella* standard. The Fifth Circuit Court ruled that the *Salmonella* standard was invalid because it constituted regulation of the characteristics of raw materials and not regulation of sanitary conditions in the plant, as suggested by FSIS. Although FSIS has authority to regulate the characteristics of raw materials, the meat trimmings contaminated with *Salmonella* in this case came from a plant that had passed FSIS inspection. The Supreme Beef decision led FSIS to modify its enforcement program. A news release published on the FSIS website (fsis.usda.gov, April 2, 2002) indicated that the Supreme Beef decision does not prevent FSIS from suspending inspection services or withholding marks of inspections for failure to develop and implement SSOPs and HACCP plans. The decision affects only enforcement of the *Salmonella* standard but not FSIS's ability to test for *Salmonella*.

[2] Under the WMA and WPPA, managers were also responsible for sanitation in that their plant had to meet appropriate sanitary conditions for the production of meat and poultry products.

Performance Under the WMA of 1967 and WPPA of 1968 and PR/HACCP

FSIS inspectors have monitored sanitary conditions since the enactment of the WMA and WPPA and now also verify performance of HACCP tasks. Under the WMA and WPPA, FSIS assigned critical deficiencies to plants that did not perform or had poorly performed essential sanitation and process control tasks. The data used here were developed especially for this report by FSIS and are defined as the number of critically deficient sanitation and process control practices divided by all such practices. Critically deficient sanitation and process controls practices are either failures to perform or poorly perform tasks that are most important to reducing health risks to consumers. There are also minor and major deficiencies not deemed to be as high of a risk to human health and are not considered in this report.

Table 3.1 shows how percent critical sanitation and process controls practices (percent critical deficiencies) vary by type of industry and plant size. Table 3.1 includes the mean critically deficient sanitation and process control tasks as a share of total sanitation and process control tasks for selected industries. All plants in the tables have animal slaughter, processing, or animal slaughter and processing operations, but most do not derive a majority of their income from the manufacture of meat products or animal slaughter. Plants in industries with SIC codes that begin with 20 have food manufacturing as their primary business, those starting with 51 are mainly distributors, and those leading off with 54 have retail marketing as their major interest.[3] The table shows that poultry slaughter plants have the highest number of percent critically deficient sanitation and process controls. Other data in the table include mean plant sales in 1999, mean plant pounds of meat produced in 1996 (such data do not exist for 1999) and the number of establishments. The table does not include very small plants, those with fewer than 10 employees or sales of less than $2.5 million, because they had not converted to HACCP by 1999 and, thus, had not been inspected when the data became available.

Table 3.2 shows how critical sanitation and process control deficiencies vary by plant size for slaughter and processing plants. The data indicate that the very smallest plants had about a third the percentage of critical deficiencies as the largest plants, and there exists a trend in which larger plants, in general, had a greater share of critical deficiencies than smaller ones.

[3] All of the businesses in tables 3.1 and 3.2 process meat or slaughter animals or do both. However, they may be classified as a distributor because the plant derives most of its revenue from distribution. For these facilities, meat processing or animal slaughter operations are secondary businesses.

Summary

In chapter 2, we discussed food safety regulatory history up to about 1990. This chapter presented a chronology of foodborne illness outbreaks that increased the public's awareness of such illnesses and discussed major regulatory changes during the 1990s. Current food safety regulation has its roots in the Federal Meat Inspection Act (FMIA) of 1906 and the amendments to the FMIA enacted through the WMA and WPPA of 1967 and 1968. Rather than being a complete break from the past, promulgation of the PR/HACCP rule of 1996 marked an acceleration in the long-term shift in regulatory focus away from visual animal and meat inspection and toward efforts dealing with the threat of foodborne illness posed by harmful pathogens.

The principal element of the PR/HACCP rule of 1996 was the use of a mandatory HACCP program. Other aspects of the rule included the use of sanitation procedures, a *Salmonella* standard to verify the effectiveness of the HACCP program, and mandatory generic *E. coli* testing to ensure compliance with the zero fecal matter standard. The mandated HACCP plan had been recommended to FSIS by various organizations since the 1970s. It included: (1) assessing all hazards, (2) finding all critical points, (3) setting critical limits for each critical control point (CCP), (4) developing procedures to monitor each CCP, (5) determining corrective actions, (6) implementing a recordkeeping system, and (7) establishing verification procedures (Unnevehr and Jensen, 1996).

Compliance with sanitation and process controls under WMA and WPPA varied according to product market and plant size. The share of critically deficient sanitation and process control tasks was much higher for poultry slaughter than for other plants. Segmenting the data into five size categories showed that smaller plants had a lower share of critically deficient sanitation and process control tasks than their larger competitors. The range varied from larger plants having three times more for red meat animal slaughter to about twice as many for meat processing.

Table 3.1—Percent critically deficient SPCPs for selected industries[1]

Industry	SIC[2]	Total facilities	Plant mean		
			1996 pounds of meat and poultry	Estimated 1999 sales	1992 critically deficient SPCP
		Number	*Millions*	*Millions $*	*Percent*
Red meat slaughter	2011	201	225.7	198.2	4.0
Meat processing	2013	652	23.8	48.6	2.8
Poultry slaughter and processing	2015	82	203.0	113.6	5.7
Frozen meals, pizza, etc.	2038	85	19.3	51.0	1.6
Grocery distributor	5141	107	15.6	103.6	2.2
Frozen food distributor	5142	25	9.1	49.5	2.1
Poultry products distributor	5144	55	54.4	98.1	3.6
Meat products distributor	5147	462	7.5	34.5	2.3
Meat and fish markets	5421	117	15.3	12.1	2.1

[1] Data include only those plants that existed in 1992, had converted to HACCP, and were being inspected by FSIS in 1999. These include the large and small plants but not the very small plants.
[2] SIC codes are based on Enhanced Facilities Database estimates.

Source: U.S. Department of Agriculture, Food Safety and Inspection Service.

Table 3.2—Percent critically deficient SPCPs for selected sizes of meat and poultry plants[1]

Volume	Plants	Plant mean			
		1992 output	1999 output	1999 estimated sales	1992 critically deficient SPCP
		Number		*Million $*	*Percent*
Hoofed animal slaughter plants:					
Number of hoofed animals per year—					
Fewer than 1,000	59	36,887[2]	399	4.7	2.0
1,000-9,999	76	8,212	3,773	7.5	2.7
10,000-99,000	78	36,403	43,254	23.5	3.1
100,000-1 million	66	194,334	332,274	135.5	4.8
More than 1 million	49	1,864,332	2,477,539	774.0	6.5
		Dollars			
Only meat-processing plants:					
Value of output in dollars per year—					
Fewer than 2.5 million	127	15.8	17.2	1.3	2.3
2.5 million - 9.9 million	117	2.8	3.1	6.3	2.4
10 million - 49 million	288	12.6	14.3	23.3	2.7
50 million - 100 million	85	33.0	35.6	70.6	3.6
More than 100 million	73	72.9	89.1	206.6	4.2
		Number			
Bird slaughter volume:					
Number of birds per year—					
Fewer than 2.5 million	61	0.55	0.44	31.9	3.1
2.5 million - 7.4 million	33	4.62	5.42	90.9	2.9
7.5 million - 34.9 million	48	15.1	15.0	115.6	4.6
35 million - 50 million	88	31.7	37.2	156.3	7.0
More than 50 million	59	53.3	69.0	178.7	8.6

[1] Data include only those plants that had converted to HACCP and were being inspected by FSIS in 1999, and existed in 1992. These include the large and small plants but not the very small plants.
[2] Some plants made transitions from plants slaughtering thousands of animals in 1992 to plants with miniscule slaughtering operations in 1999.

Source: U.S. Department of Agriculture, Food Safety and Inspection Service.