

SEAFOOD ROULETTE THE VICTIMS' STORIES

CASE STUDIES OF
SEAFOOD-BORNE ILLNESS
AND
GOVERNMENT INACTION

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SEAFOOD-BORNE ILLNESS: A GROWING NATIONAL SCANDAL

The ongoing threat of serious seafood-borne illness in the United States is nothing short of a national public health scandal. Each year, significant numbers of unsuspecting consumers are stricken with grave illnesses from eating seafood contaminated with viruses, fecal bacteria, parasites and potent naturally occurring poisons. Some of the victims have died, others have been left with lifelong handicaps and still others have been fortunate enough to recover from long bouts with debilitating diseases. Worse yet, their suffering was, for the most part, unnecessary. In most cases, the illnesses could have been prevented if the nation's seafood supply had been safeguarded effectively by a mandatory seafood safety program.

This report documents seven incidents of serious seafood-borne illness. Each case study describes the circumstances causing the illnesses and the victims' symptoms. In each instance, the illness was caused by contaminated seafood that slipped undetected through the country's porous regulatory net.¹ This report examines inadequacies in government programs that continue to allow contaminated seafood to reach consumers.

While the exact number of seafood-borne illnesses remain unknown (due to inadequate government surveillance) there is little reason to believe that the situation described in this report will improve in the future without decisive federal intervention. In fact, as seafood consumption increases in response to consumer demand for lower fat flesh food products, the number of victims is likely to increase.

As if to add insult to these victims' injuries, federal authorities have consistently failed to take the steps necessary to ensure that more unsuspecting consumers will not join their ranks. For a number of years, there has been a growing consensus among experts that the current patchwork of mostly voluntary seafood safety programs does not protect consumers adequately. Research reports documenting the public health hazards

and the inadequacy of governmental protection (including studies by the National Academy of Sciences, *Consumer Reports* magazine and Public Voice) and extensive media coverage of seafood safety problems have generated recent flurries of federal activity. Bills were introduced in Congress during its last two sessions, the Food and Drug Administration created the Office of Seafood and the Bush Administration has increased its spending on seafood safety.

For all of this increased federal attention, however, little has changed in the level of protection provided to consumers of domestic and imported seafood products. Regular federal inspection programs remain mostly voluntary and fail to cover nearly 80 percent of the seafood consumed in the U.S.; the federal system continues to be reactive and piecemeal rather than proactive and comprehensive; federal sampling programs to detect contamination are grossly inadequate; and effective surveillance mechanisms needed to properly track illnesses and identify problems in the system are still not in place.

In short, the country still lacks the comprehensive mandatory seafood safety program that offers the only hope for getting the problems of seafood-borne illness under control. Only Congress can bring such a program into being. Yet, for the second legislative session in a row, Congress is failing to enact a seafood safety law.

The fate of seafood safety legislation in the 102nd Congress illustrates how the American public is victimized by a national food policy process in gridlock. Last spring, S. 2538, the Consumer Seafood Safety Act of 1992, was introduced, with bipartisan support, by Senators Mitchell (D-ME), Hollings (D-SC), Leahy (D-VT), Kennedy (D-MA), Kerry (D-MA), Cohen (R-ME), and Stevens (R-AK). The bill represented a consensus resolving many of the issues which had divided members of Congress in the previous session. With the strengthening of some of the bill's enforcement and standard-setting provisions, this comprehensive legislation would have provided consumers with the strong, mandatory program needed to enhance the safety of the nation's seafood supply.

Unfortunately, S. 2538 was never considered by the full Senate. A combination of forces doomed the bill to a premature death in committee, including:

- ▶ Vigorous opposition by FDA and deregulation-minded Bush Administration officials who did not want to see a strong, comprehensive program enacted;
- ▶ A counterproductive push by seafood industry lobbyists for a weak program that would provide a federal seal of approval without adequate protections to make it meaningful;
- ▶ Stiff resistance from meat and poultry interests, who lobbied against strong standard-setting and enforcement provisions to prevent the establishment of a precedent for stronger regulations in their own industries; and

- The inability of Congress to overcome opposition from food industry interests and a pro-business Administration.

This report seeks to illuminate the real human costs of chronic federal government inaction. The first-ever series of case studies of the victims of seafood-borne illness, this report depicts the serious -- and sometimes calamitous -- implications of the continuing gaps in federal seafood safety policy.

CONTAMINATED SEAFOOD: MULTIPLE PUBLIC HEALTH HAZARDS

Shellfish and finfish carry natural toxins and microbiological and chemical contaminants that can cause a wide variety of illnesses in humans. The severity of the illnesses range from unpleasant gastrointestinal distress that lasts one or two days to infections and poisonings that can be seriously debilitating and even fatal. In addition, chronic exposure to the environmental pollutants which accumulate in seafood may cause cancer and nervous system damage to humans, as well as developmental problems in the children of those consumers who eat contaminated seafood prior to and during pregnancy.

Microbiological Contaminants. Seafood becomes contaminated with microbial pathogens through three major sources: 1) fecal and other human pollution of waters where fish swim; 2) natural microbiological contamination of these waters; and 3) contamination through handling and processing. Diseases such as cholera, vibrio vulnificus and hepatitis A (each of which is documented in a case study in this report) as well as Norwalk viruses occur most frequently through consumption of raw or incompletely cooked shellfish that has been contaminated in the marine environment. Diseases such as campylobacteriosis (see case study), botulism and shigellosis, as well as hepatitis A, often result from improper processing, handling and preparation of finfish and shellfish. These diseases can be especially harmful to individuals with compromised immune systems, such as the elderly, very young children, cancer patients and those infected with HIV and other immunodeficiency diseases.

Naturally Occurring Poisons. Natural toxins develop in seafood through the natural metabolic processes of the fish itself, the fish's consumption of microorganisms that produce toxins or from chemical reactions that occur through improper handling of seafood. While shellfish are also known to carry potentially life-threatening toxins, finfish accounted for 96 percent of all cases of illness from naturally occurring poisons

reported to the Centers for Disease Control between 1978 and 1987. These naturally occurring poisons can cause diseases such as ciguatera (see case study), scombroid fish poisoning (see case study), amnesic shellfish poisoning (see case study) and paralytic shellfish poisoning. Severe cases can lead to long-term disability and even death.

Chemical Contamination. Toxic chemicals in seafood have the potential to cause cancer, long-term illnesses like Parkinsonism and developmental disorders in children that result from long-term exposure.² The relationship between these illnesses and the consumption of contaminated seafood is only beginning to be explored. Unlike acute seafood-borne illnesses like the ones documented in this report, it is very difficult to pinpoint the specific cause of a long-term illness such as cancer in a specific individual victim. Because chemicals can accumulate in fat and other tissue, the chemical contaminants responsible for the illness may have been consumed in years prior to the onset of the disease.

Several recent studies and the data from large-scale poisoning episodes have provided a causal link between exposure to toxic chemicals in fish and human health effects. As a result, many scientists are raising questions about the potential for harm from consuming seafood contaminated with PCBs, organochlorine pesticides such as DDT and dieldrin and heavy metals such as mercury and lead.

In testimony before Congress in April, Dr. Theo Colburn, a senior fellow with the W. Alton Jones Foundation and the World Wildlife Fund, described a study of infants born to women who had consumed two to three meals per month of Lake Michigan fish for at least six years preceding their pregnancies. The infants experienced low birth weight, shorter gestational periods, smaller skull circumference and cognitive, motor and behavioral deficits. At age four, according to Dr. Colburn, behavioral problems continued to be observed in these children. Dr. Colburn recommended that women of child-bearing age refrain from eating any contaminated fish.

Chemical contamination is pervasive in U.S. fishing and shellfish-harvesting waters. A 1992 Consumer Reports investigation conducted in New York and Chicago found PCBs in 43 percent of the salmon tested, 25 percent of the swordfish and 50 percent of the lake whitefish. Mercury was found in 90 percent of the swordfish tested; DDT and other banned pesticides were found in catfish, lake whitefish and swordfish; and lead was found in clams. These findings are consistent with data presented in the National Academy of Sciences report, *Seafood Safety*. The report found that chemical contaminants were present in seafood at all national monitoring sites.

CASE STUDIES OF SEAFOOD ILLNESS: THE VICTIMS' STORIES

The following seven case studies illustrate vividly the dangers the ineffective U.S. seafood safety program poses to consumers. They document the devastating impact of microbial and viral pathogens, such as the hepatitis virus, *vibrio vulnificus*, *campylobacter* and non-O1 *vibrio cholerae*, and natural toxins, including ciguatera, scombroid toxin and domoic acid. While these cases represent some of the major seafood-borne illnesses, they are by no means exhaustive of all of the acute public health hazards posed by contaminated seafood.

Most of these victims contacted Public Voice with their stories. Through letters and phone calls, Public Voice obtained specific details of their case histories.

Scombroid Fish Poisoning: Dr. Simpson Dies after Consuming Contaminated Tuna

Dr. William Simpson and his wife Barbara Simpson ate their last meal together at the Gallery Restaurant on Hatteras Island, North Carolina, on October 28, 1988. An hour and a half after eating the grilled tuna dinner, Dr. Simpson, a 64-year-old physician from Shelby, North Carolina, died of cardiac failure induced by scombroid fish poisoning.

The Symptoms

Dr. Simpson first noticed symptoms of the illness 30 minutes after eating. His pulse had quickened, his face was flushed and he was weak with nausea, diarrhea, abdominal cramps and severe chest pains. Dr. Simpson was experiencing an acute reaction to histamine, a poison which had accumulated in the tuna steak because the tuna had been mishandled prior to cooking. Within one hour after noticing the first symptoms of the histamine poisoning, Dr. Simpson died of cardiac arrest.

Scombroid fish poisoning normally does not result in death. Typically, victims experience scombroid symptoms for four to six hours, but occasionally the symptoms last for one or two days.³ Individual responses to scombroid poisoning vary, but certain medications and ailments render victims vulnerable to severe attack. Age may have been a factor leading to Dr. Simpson's acute histaminic reaction. Unfortunately, scombroid fish poisoning is often misdiagnosed. Many doctors are not trained to recognize the illness and instead advise patients that they have a fish allergy.⁴

The Risks

Scombroid fish poisoning is caused by the consumption of fish contaminated with histamine.⁵ Histamine is a toxin which develops naturally in the flesh of certain fish when these fish are not properly refrigerated or are exposed to harmful bacteria.⁶ Scombroid fish poisoning is associated most frequently with tuna, mackerel, mahimahi, bluefish and other fish from the scombroid family.⁷

According to the National Academy of Sciences, "The risk of scombroid poisoning is widespread among fish-eating consumers."⁸ Yet, aside from abstinence, consumers do not have the power to protect themselves. The only method to determine the presence of histamine in fish is scientific testing. Consumers cannot detect it through odor and cooking will not eliminate the poison.⁹

Scombroid fish poisoning can be avoided only by ensuring that contaminated seafood does not reach consumers. Once a fish is mishandled and becomes contaminated with excess histamine, it must be destroyed. The absence of a comprehensive mandatory

seafood safety program means that there are few checks on seafood handling and inadequate testing of seafood in the marketplace.

At present, the lack of hand-washing facilities and toilets on many fishing boats can cause fish to become contaminated with harmful bacteria when handled by workers. Fish are often left unrefrigerated on the decks of fishing boats or stored at temperatures above those required to retard bacterial growth.¹⁰ Proper sanitation and temperature control procedures could prevent harmful contamination, but currently there is no federal oversight of how fish are handled after their capture.

Consumers are also exposed to improperly handled imported fish. This past May, 79 cases of scombroid fish poisoning were reported across five Eastern states.¹¹ Investigators traced the problem to shipments of Ecuadorian fresh tuna. When the distribution warehouses were inspected, no temperature violations were found. The tuna was apparently mishandled in Ecuador,¹² passed through customs and was sold to customers uninspected.

Although state and federal officials realized that scombroid outbreaks were sweeping the coast, New Jersey residents were the only consumers warned to avoid Ecuadorian tuna. Delaware state health officials had to initiate contact with their local health departments to learn that three illnesses had been reported in the state because their local health departments are not required to notify the state of cases of scombroid poisoning.¹³

Campylobacteriosis: Mrs. Mages Hospitalized after Eating Canned Tuna

Mrs. Jean Mages rarely eats seafood, but the canned tuna she prepared on October 24, 1986, caused her to be hospitalized for five days. The tuna contained *campylobacter jejuni*, a strain of bacteria derived from human sewage, and it sent Mrs. Mages into a near-lethal bout with campylobacteriosis.¹⁴

The Symptoms

Mrs. Mages, who lives in Phoenix, Arizona, woke up in the middle of the night with severe stomach pains two days after eating the tuna. She became weak with diarrhea, vomiting and a 102-degree fever, and she could neither eat nor drink water. Mrs. Mages breathes with the aid of an oxygen tank, and she is very susceptible to dehydration.

When her husband took her to the hospital the following evening, doctors told her that she might have died if she had delayed seeking medical attention. After five days, campylobacteriosis was identified as the cause of her illness, but Mrs. Mages could not take medication to combat the bacteria because she was allergic to it. She eventually recuperated on her own.

For most healthy individuals, campylobacteriosis symptoms will pass after 24 hours. For others, especially young children and adults with weakened immune systems, *campylobacter* presents a serious health threat. The illness may even cause relapsing colitis, a chronic digestive disorder.¹⁵

The Risks

Outbreaks of campylobacteriosis have been linked to shellfish and surface water, and *campylobacter* may also be found in freshwater fish and crustaceans.¹⁶ According to the National Academy of Sciences, the bacteria is more likely to thrive when fish is packaged and stored at poorly controlled temperatures.¹⁷

Mrs. Mages was able to identify canned tuna as the source of her fish poisoning because she had not eaten seafood for some time. The manufacturer, Carnation Tuna Company, told Mrs. Mages that the fish had been caught and canned in Puerto Rico. While the company would not tell Mrs. Mages whether anyone else had reported similar problems, it did pay her medical bills of \$3,600. It was never determined whether the bacteria had been present in the tuna itself or in the water in which the tuna was packed.

Ciguatera: Dr. Minton Crippled by Natural Toxins in Fresh Fish

Dr. Ty Minton of Westmoreland, New Hampshire, has visited various Caribbean islands regularly since 1963 and has sampled many native seafood specialties. Over time, he began to develop numbing and tingling in his hands but he never recognized the cause of the problem or realized its significance.

In January 1984, Dr. Minton ate a dish called "white fish" while leading students on a tour of Turtolla in the British Virgin Islands. This particular meal, along with subsequent dinners of mahimahi in Miami, Florida, in February 1984 and yellow snapper in Dallas, Texas, in March 1984, sparked what was to become Dr. Minton's life-long battle with ciguatera.

The Symptoms

Shortly after the "whitefish" meal, Dr. Minton felt feverish and nauseated. Several days later, he began to experience a lack of coordination, disorientation and heightened sensory disturbance in his hands, and he suffered from fevers and sweating. The symptoms became more severe after each of the meals in Miami and Dallas. The three seafood meals were all contaminated with naturally-occurring poisonous toxins that attacked Dr. Minton's neurological system. Between January and April 1984, Dr. Minton spent much of his time bedridden.

The disease known as ciguatera is the manifestation of symptoms induced by excessive exposure to ciguatoxin, a naturally occurring poison found predominantly in tropical fish. Dr. Minton had accumulated a significant quantity of the toxin in his body because he frequently ate fish that carried traces of the toxin. The only sign of the toxin was the numbing of his hands. However, when he ate the highly toxic "white fish," his body surpassed its threshold tolerance for the poison. He then began to fully experience the painful and disabling effects of ciguatera. The meals in Miami and Dallas raised the level of toxin in his body even further. Dr. Minton regained his ability to walk after several months, but other symptoms did not dissipate for two years.

Dr. Minton sought medical treatment upon his return to the United States, but his doctor assured him that he only suffered from a virus and suggested that Dr. Minton should just "wait it out." By April, the symptoms did begin to abate, but Dr. Minton was convinced that his illness was more than a virus. He sought the advice of a neurosurgeon, who initially thought Dr. Minton might suffer from multiple sclerosis or a viral spinal infection. Dr. Minton was hospitalized for three days of intensive testing. Ciguatera cannot be detected through medical testing, however, so Dr. Minton's test results were normal. In order to diagnose ciguatera, the physician must be familiar with the disease and be able to associate the symptoms with the illness.¹⁸ Few doctors in the U.S. mainland are able to do so. Fortunately, Dr. Minton's case was referred to a

neurologist who had worked in Miami and who was familiar with ciguatera. Four months after becoming ill, Dr. Minton was finally diagnosed as having contracted ciguatera.

The Risks

Ciguatera is a syndrome caused by eating fish containing concentrated amounts of neurotoxin. The toxin does not harm the fish, but it is poisonous to humans. Fish acquire the toxin by feeding off certain reef and island algae. Hundreds of species of tropical and island water fish may cause ciguatera, but the toxin tends to concentrate more heavily in larger fish.¹⁹

Once ingested, ciguatoxin characteristically affects both the gastrointestinal and neurological systems of its victims. The severity and duration of the neurological symptoms varies among individuals.²⁰ Because the toxin may linger in the body for years from each minor exposure, individuals like Dr. Minton who eat large quantities of tropical fish are especially prone to severe consequences once their bodies reach a threshold tolerance for the toxin.²¹

People who have become acutely ill from ciguatera often become particularly sensitive to traces of the toxin and are vulnerable to severe relapses.²² Dr. Minton suffered a relapse three years after the original incident when he ate lobster in Maine that was tainted with red tide toxin. He also became ill simply by losing weight: residues of the neurotoxin are stored by the body in fatty tissue, and when this tissue is reduced, the toxin returns to the blood stream. Because the threat of relapse is ever-present, Dr. Minton can no longer eat any type of seafood. Some ciguatera symptoms continue to plague him, and they may last for years. As Dr. Minton states, "Ciguatera is a lifelong disease."

Domestic outbreaks of ciguatera occur mainly in the tropical regions where ciguatoxic fish originate and are most frequently consumed: Florida, Hawaii, Puerto Rico, the Virgin Islands and Guam.²³ While ciguatera is predominantly a regional problem, mainland consumers may be exposed to the toxin by fish shipped from high-risk areas.²⁴

Because the presence of ciguatoxin cannot be detected in the taste or texture of fish, and cannot be removed by cooking or freezing,²⁵ consumers would best be protected from ciguatera by a sampling program that screens fish caught in high-risk areas. Japan employs such a program, but nothing similar has been adopted in the United States for either domestic or imported fish.²⁶

Cholera: Mr. Kilpatrick Nearly Dies from Infected Oysters

In June 1988, Mr. William Kilpatrick was at a Holiday Inn in San Francisco on vacation. While lounging by the pool, he ordered raw oysters from the room service menu. Later, in his room, he had a second order. Mr. Kilpatrick, now a recovering alcoholic, had been drinking heavily throughout the day. Mr. Kilpatrick never suspected that the oysters might be contaminated with non-O1 *vibrio cholerae*, a form of bacteria commonly found in raw oysters, clams and mussels.²⁷

The Symptoms

During the night, Mr. Kilpatrick became nauseated and began vomiting. He woke up the next morning with burning red rashes on his legs and feet. Severe pain shot up and down his legs, a sensation he compares to standing in water charged with electrical shocks. Mr. Kilpatrick could not eat or drink water for several days, and he continued to experience severe pain.

When Mr. Kilpatrick went to the hospital five days after eating the oysters, the rashes on his legs had become huge blisters. Some of the blisters were the size of baseballs and filled with blood. Doctors told him that he would have died that afternoon if he had not sought medical treatment.

Tests showed that Mr. Kilpatrick had contracted a form of cholera from the vibrio bacteria in the raw oysters. Septicemia had infected the tissue in his legs, bone marrow, central nervous system and lungs. Photographs taken during that time show large open sores covering his legs, some so deep the bone is exposed. Doctors had to operate, removing skin, muscle and some of his leg tendons because the tissue was dead. Mr. Kilpatrick spent three painful months in the hospital.

Three years later, Mr. Kilpatrick walks only with the aid of a cane and must use a wheelchair for activities that would otherwise require him to be on his feet all day. He has been unable to return to his work as a chef or to his favorite sports, tag football and tennis. Sadly, Mr. Kilpatrick is not expected to improve. "I don't think I'm going to get any better than I am," he acknowledges.

The Risks

The non-O1 *vibrio cholerae* bacteria is particularly harmful to those individuals with liver damage and weakened immune systems. These high-risk groups are more likely to develop septicemia from *vibrio* exposure, and 50 percent of those who contract septicemia die.²⁸

For healthy people, exposure to *vibrio* bacteria usually results only in the nausea, vomiting and diarrhea commonly associated with gastroenteritis,²⁹ but many who eat raw shellfish may not realize they have liver damage or weakened immune systems and thus are putting themselves at serious risk. Notwithstanding his history of alcoholism, Mr. Kilpatrick has never been diagnosed as having liver damage or cirrhosis.

The oysters Mr. Kilpatrick ate have been traced back to the Gulf of Mexico, off the Louisiana coast. Oysters caught in the warm summer months are more likely to be contaminated with this bacteria because it multiplies faster in warm weather. A 1980 FDA study found non-01 *vibrio cholerae* in up to 37 percent of U.S. oyster lots harvested during the summer.³⁰ To make matters worse, oyster harvesters sometimes do not have refrigeration equipment on their boats and can be out at sea for up to two days.³¹

Presently the federal government does nothing to protect consumers from *vibrio* bacteria. The National Academy of Sciences notes that "[t]here are currently no programs attempting to limit exposure of the general population to non-01 *V. cholerae*,"³² aside from informal recommendations to high-risk groups that they not eat oysters.

Mr. Kilpatrick had never been warned of the risks associated with raw oysters. He says he would not have eaten the oysters if there had been a warning label on the menu. "I really would like to see warning labels," he said. "I was extremely lucky. Most of the time, when you're in the situation I was in, you're dead."

Vibrio Vulnificus:

Mr. Boynton Disabled By Contaminated Oysters

Mr. Claude Boynton, a 55-year-old Florida man, was another victim of the *vibrio* bacteria, *vibrio vulnificus*. On August 19, 1989, he had a snack with his wife and son at Bernard's Surf Restaurant in Cocoa Beach, Florida. He was pleased to find a raw bar inside the restaurant and he ate two dozen raw oysters on the half shell.

The Symptoms

Two days later, Mr. Boynton was struck with a 106-degree fever and severe pain in his feet and legs. His feet and legs became discolored and swelled. He could not walk or put on his shoes. He went to a medical clinic the next day and was immediately placed in the Intensive Care Unit, where he remained for several days. Doctors later told him that at one point he was two hours away from death.

The hospital frantically ran tests until *vibrio vulnificus*, a strain of bacteria found in raw oysters and other shellfish, was identified as the culprit. Meanwhile, huge black and blue blisters began to protrude from his legs. They later developed into large, open sores.

Mr. Boynton underwent surgery at least six times during his two-month hospital stay to repair the damage done to his legs. He then had to learn to walk all over again. Three years later, Mr. Boynton still cannot move his feet easily.

Mr. Boynton owns a food and beverage vending company, and because of the illness he was unable to work for several months. If his children had not been able to keep the business in operation during that time, he would have permanently lost his income as well.

The Risks

Mr. Boynton now knows that his diabetes and liver problems place him at risk of serious illness upon exposure to *vibrio vulnificus*. But the restaurant never told him that raw oysters could be dangerous.

Heavy alcohol users and people with liver disease, blood diseases and weakened immune systems are all highly susceptible to *vibrio vulnificus*.³³ Currently, no federal mandated warning labels are required on menus or packages of raw shellfish to warn high-risk groups about the dangers of *vibrio vulnificus*, although several states have mandated the use of warnings in the sale of shellfish.

The *vibrio* bacteria is found in the Gulf coast waters and along the Atlantic and Pacific coasts, and it is more commonly found during the warm summer months.³⁴ Currently, there exists no government program adequate to prevent contaminated shellfish from reaching consumers, making a repeat of Mr. Boynton's experience a practical certainty for other unsuspecting raw oyster eaters.

Hepatitis A: Ms. Baranauskas Hospitalized from Eating Infected Clams

Last spring, Ms. Bridget Baranauskas contracted hepatitis A after she ate clams in the shell with linguine at a Baltimore restaurant. The clams were lukewarm.

The Symptoms

In June, approximately 45 days after the meal, Ms. Baranauskas began to experience flu-like symptoms and extreme fatigue. She went to a hospital and remained there for a week. Her condition was diagnosed as hepatitis A, a serious viral infection of the liver. Ms. Baranauskas was seriously ill for a month and could not work, and she eventually was forced to drop out of law school because she was too exhausted to study.

Hepatitis A is a viral disease characterized by fever, nausea and vomiting. It has a 15- to 45-day incubation period, so it is often difficult to determine whether raw seafood is the source of the disease.³⁵ Hepatitis A can be a serious and prolonged illness, but the mortality rate is low.³⁶ Ms. Baranauskas' liver enzymes did not return to normal for over six months.

The Risks

Hepatitis A is contracted by the ingestion of food or water contaminated with human feces. It is spread through poor personal hygiene of food handlers, inadequate cooking of infected food and contaminated shellfish growing waters.³⁷ The incidence of hepatitis could be reduced through more rigorous government action in establishing safe handling procedures, inspecting processing facilities and closing and policing waters contaminated by raw sewage.

Amnesiac Shellfish Poisoning: Eleven Washington State Residents Stricken by Natural Toxins in Razor Clams

In the fall on 1991, at least 11 people in Washington state ate razor clams containing a deadly toxin known as domoic acid. Domoic acid causes an illness called amnesiac shellfish poisoning (ASP), so-named because its most distinctive symptom is loss of short-term memory. Domoic acid directly affects the brain when ingested, short-circuiting the brain receptors and destroying the part of the brain that controls short-term memory loss.³⁸ Washington state officials had detected domoic acid in a sample, but they waited 18 days after the first sample was taken,³⁹ in the peak of the razor clam season, to close the harvesting waters. —

The Symptoms

Only two of the 11 victims in Washington became ill enough to experience neurological symptoms which, in addition to memory loss, can include headache, dizziness, facial grimace, disorientation, excessive bronchial secretions, difficulty in breathing and coma.⁴⁰ The other nine victims had mild cases, which can consist of nausea, vomiting, abdominal cramps, diarrhea and anorexia.

Fortunately, according to state officials, these Washington victims eventually recovered from amnesiac shellfish poisoning. Some ASP victims are not so lucky. An ABC "20/20" television program aired in 1990 reported that over 150 Canadian victims contracted ASP after eating mussels containing extremely high levels of domoic acid. Three persons died, and some victims fell into comas and never recovered. Many of those who did regain consciousness lost their short-term memories, with dramatic effects: one man lost his business when he could no longer remember how to conduct simple business transactions; another recounted the frustration of not being able to watch a TV show because he could not follow the story line.⁴¹

Shellfish may also carry three other types of poisonous toxins, all with symptoms similar to those of ASP. Paralytic shellfish poisoning (PSP) causes the same neurological symptoms as ASP, but it is even more poisonous and can cause respiratory paralysis and death.⁴² Neurotoxic shellfish poisoning (NSP) causes neurological symptoms.⁴³ Diarrhetic shellfish poisoning (DSP) causes diarrhea, nausea, vomiting and abdominal pain.⁴⁴

The Risks

The poisons which cause ASP, PSP, NSP and DSP illnesses are derived from natural processes. When shellfish feed on certain types of algal blooms, residues of the algae become concentrated in the shellfish and form poisonous toxins.⁴⁵ These toxins do not affect the shellfish, but they are poisonous when ingested by humans.

The presence of toxic algal blooms, commonly known as "red tides," may indicate that local harvesting beds are contaminated. Satellites and other technology have made it possible to better monitor algal blooms,⁴⁶ but scientists are not yet able to predict them.⁴⁷ Alarmingly, toxic algal blooms have dramatically increased over the past five years. They now appear with greater frequency near harbors that have experienced increased human population growth, and they have spread to new regions. Even some formerly benign species of algae have turned toxic.⁴⁸ Domoic acid, the toxin that causes ASP, was only first detected in 1987.⁴⁹ Many scientists fear that the increase in toxic algal blooms is another irreversible global trend.⁵⁰

Shellfish consumers cannot protect themselves from poisonous shellfish toxins; the poison can not be eliminated by normal cooking,⁵¹ nor can it be detected by sight or smell. The risk of illness can be avoided only through the monitoring and closure of harvesting waters and sampling, inspection and oversight of all domestic and imported shellfish.

Canadian officials have monitored levels of domoic acid ever since the ASP epidemic occurred, and they have banned the harvest of mussels at least twice.⁵² Americans are not so well protected. Domoic acid can be detected in a laboratory, but according to *Seafood Safety*, only Northeastern states test for the toxin.⁵³

The toxin causing PSP is found mainly along the coasts of New England, Alaska, California and Washington.⁵⁴ The DSP toxin appears off the Florida coast and in the Gulf of Mexico, but it has been known to travel to nearby states.⁵⁵ Commercially-produced shellfish are regularly tested for toxins in these areas. The toxins causing DSP are concentrated in Japan and Europe, but one DSP case was recently reported in Canada. Insufficient regulation of imported clams and mussels poses the greatest risk of DSP to consumers, but a domestic outbreak is possible given the changing nature of algae patterns.⁵⁶

THE VICTIMS THAT GOT AWAY: INEFFECTIVE FEDERAL SURVEILLANCE OF SEAFOOD-BORNE ILLNESS

The exact number of seafood victims nationwide continues to remain a mystery as a result of the inadequacy of the federal disease surveillance system. At least half of the individual victims documented in this report, for example, were never reported as having seafood illnesses to the Centers for Disease Control.

Underreporting of seafood-borne illness is widespread throughout the country's state public health agencies. Since federal public health agencies, such as CDC and FDA, base their assessments of the extent of seafood-borne illness on officially reported cases from state or local health departments, such reporting failures inevitably lead to massive underestimates of the actual incidence of seafood illnesses. This serious deficiency in public health surveillance and risk assessment was confirmed by Public Voice's recent survey of 49 state health departments and the District of Columbia.

Specifically, Public Voice found the following barriers to the reporting of seafood-borne illnesses:

- ▶ The food source causing a food-borne illness usually is not defined. Health officials in 66 percent of the states said that the food responsible for an illness could not be detected at least half the time.
- ▶ Most illnesses that are primarily seafood-borne are not required to be reported. Only two states have ciguatera on their list of reportable illnesses; two listed scombroid poisoning; 14 list vibrio-related illnesses; and none list Norwalk viruses. None of these illnesses are on the Center for Disease Control's list of nationally notifiable diseases.

- ▶ Doctors often don't diagnose or report seafood-borne illness to state health departments. Nearly 70 percent of state health departments said that doctors do not realize that seafood-borne illnesses should be reported. Eighty-three percent said that doctors do not diagnose seafood-borne illnesses.
- ▶ Forty-two percent of state health departments identified lack of enforcement of reporting requirements and 51 percent identified underfunding of their departments as barriers to complete reporting of food-borne illnesses.

The absence of a comprehensive, reliable surveillance system for seafood-borne illness leaves consumers at greater risk of being victimized by contaminated seafood. Without complete information about the actual incidence of seafood-borne illnesses, federal regulators are unable to accurately assess the risk to consumers and they cannot effectively target their consumer protection activities. Moreover, the federal government's failure to account for the victims of seafood-borne illnesses invariably leaves the public in the dark about the extent of the problem and prevents federal regulators from being held fully accountable for the inadequacies of their public health programs.

PREVENTING NEEDLESS TRAGEDIES: THE NEED FOR STRONG, COMPREHENSIVE LEGISLATION

The current patchwork of mostly voluntary state and federal seafood safety programs lacks many of the regulatory elements that are essential for protecting consumers against the types of debilitating diseases documented in this report. Among other things, the existing programs do not include:

- ▶ Federal standards for safe handling procedures on fishing vessels;
- ▶ Frequent unannounced inspections of processing plants, fishing vessels or foreign plants processing seafood for export to the U.S.;
- ▶ The requirement that Hazard Analysis Critical Control Points (HACCP) programs be used by all processing plants to reduce the likelihood of contaminating seafood during processing;
- ▶ Strong, explicit standards for microbial and chemical contaminants in seafood as well as the effective sampling programs needed to detect contamination;
- ▶ Mandatory monitoring and inspection of shellfish harvesting under strong federal leadership;
- ▶ Certification and registration of all shellfish handlers and processors;
- ▶ A label on packages and menus alerting vulnerable consumers of the dangers of eating raw or undercooked molluscan shellfish.

Standards for Fishing Vessels

One critical measure needed to stem the occurrence of seafood-borne illnesses like scombroid fish poisoning is the standardization of safe handling procedures aboard fishing vessels. Standards for fishing vessels are essential to minimize the potential risk to consumers from scombroid poisoning and other illnesses caused by mishandling. If vessels were required to carry fresh water for hand-washing, make-shift toilet facilities and freezers for storing fish, contaminants that cause seafood-borne illnesses such as scombroid poisoning could be thwarted at their onset. To ensure that basic health measures such as those above are implemented, enforcement of these standards through unannounced inspections of fishing vessels is essential.

Monitoring and Closure of Fishing Grounds and Harvesting Waters

To help identify "hot spots" for ciguatera toxins and chemical contaminants, fishing grounds must be monitored and samples of seafood from those waters must be taken. If a significant health risk is discovered, the waters should be closed to commercial and recreational fishers alike. Surveillance of the waters must be employed to enforce the closure.

Shellfish harvesting waters should be monitored and classified according to their suitability for harvesting. If certain areas are found to present a significant health risk, they must be closed to harvesting for as long as that risk persists to assure that consumer health is not jeopardized.

Inspections of Domestic and Foreign Processing Facilities

Frequent, unannounced inspections of domestic seafood processing facilities by federal inspectors can help prevent illnesses related to processing like campylobacteriosis and botulism. Domestic facilities that process fish products should be registered and subject to random inspection and sampling. Imported fish products should be inspected and sampled at the port of entry and foreign processing plants should be subject to random inspection to ensure that they meet national standards. While periodic inspections and sampling alone will not eliminate the risk of seafood-borne illness entirely, they will aid in the detection of food safety violations which lead to contaminated seafood reaching the market.

Mandatory "Hazard Analysis Critical Control Points" Programs

Inspection of seafood processing plants is supplemented by a "hazard analysis critical control points" system, known as HACCP, that mandates that seafood processors institute a program to identify and monitor critical points where contamination is likely to occur. Although HACCP has been strongly recommended by FDA, the program is voluntary at present. In addition, HACCP programs need to be strengthened by protection of the rights of whistleblowers, who provide an additional check on the safety procedures implemented by plant operators.

Strong Contamination Standards

Although FDA has authority to set standards for chemical and microbial contaminants in seafood, the agency has only one legal limit -- or tolerance -- and 13 informal action levels. FDA should be required to set standards for substances, including chemical contaminants, that may render fish unsafe for human consumption. These standards should be set at levels that protect groups such as pregnant women, children and the elderly, which are sensitive to exposure to particular contaminants, and groups that consume above-average levels of seafood and who therefore have higher-than-average exposure to contaminants.

Extensive Sampling for Contaminants

Strong standards are critical to ensuring that potentially hazardous seafood, once tested, can be removed from the market. However, in the absence of adequate sampling or testing, the strongest standards will be ineffective. Sampling seafood at many points from water-to-table is essential, including taking samples from harvesting waters to identify sources of contaminated fish; at processing plants to identify inadequacies in the HACCP program and in processing practices; at import centers to find contaminated imports; and even at the marketplace to identify retail and shipping practices that contaminate seafood.

Regulation of Imported Seafood

Over half of all seafood consumed in the United States is imported. Yet, these imports are subject to only minimal inspection at the port of entry. The inadequacy of this system was clearly demonstrated by the outbreaks of scombroid fish poisoning that occurred in five states in May 1992 and by the indictments in June 1992 when several FDA inspectors who allowed at least 20 tons of contaminated seafood to be imported into the U.S. These examples demonstrate the urgent need for more rigorous import control.

The establishment of a certification program for foreign countries would meet this objective. Foreign nations exporting fish products that meet U.S. standards and who consent to random sampling and on-site inspections should be certified to export their products to the United States. Products from these countries can be monitored upon their arrival to the U.S. Countries that are not certified may still be permitted access to U.S. markets, but their fish products must be subject to intense scrutiny upon arrival.

Mandatory Regulation of Shellfish

In the decade leading up to 1987, the toxins and microbial contaminants present in shellfish accounted for 66 percent of all seafood-borne illness cases reported to the Centers for Disease Control. Shellfish was responsible for four of the seven cases examined in this report. Nonetheless, the monitoring and inspection of shellfish harvesting remains voluntary, conducted on a state-by-state basis with only a limited federal role.

Public health is not protected adequately by the existing mix of state and federal shellfish regulatory programs. State agencies have been shown to fall prey to commercial and political pressures, delaying or avoiding the closure of harvesting waters despite evidence of harmful contamination. This problem was amply demonstrated in the spring of 1991 when Louisiana delayed closing its harvesting waters for weeks after FDA issued an advisory urging the Gulf states to do so.

That spring of 1991, torrential rains occurred in states along the Gulf of Mexico and caused severe flooding. FDA recommended that states conduct a precautionary closing of their oyster beds. The oysters were at high risk of contamination from fecal chloroform runoff, and the deluge of fresh water itself would likely cause the oysters to become "stressed" and die. Every state but Louisiana, the state which produces almost half the country's supply of oysters, complied with the recommendation. Louisiana initially prepared to close the oyster beds, but after a state politician intervened, the plans for an emergency closure were cancelled. Although Louisiana did ultimately close the beds, it was only after FDA renewed its pressure by sending the state letters threatening enforcement action. The Louisiana oyster beds stayed open for several weeks after FDA's initial recommendation and the potential existed for a serious public health problem.

A mandatory shellfish safety program is needed to ensure that consumer health remains a priority in emergency situations. Improvements to the National Shellfish Program should establish mandatory standards and procedures for the growing, harvesting, handling, processing and shipment of bivalve mollusks to assure a safer shellfish supply and provide for federal enforcement of those standards. In addition, the industry should be prohibited from participating in setting governmental policy other

than in a manner consistent with the Administrative Procedures Act, as it currently is allowed to do under the existing program.

Once shellfish is harvested, it should only be shipped and processed by groups certified for their compliance with federal standards. The public will be assured that a product is in compliance with this certification through an official mark displayed on the shellfish product.

Shellfish handlers and processors should be registered so that health officials can better trace contaminated shellfish through the channels of distribution and halt unsafe practices at their source.

Compulsory Shellfish Warning Label

Although health advisories are needed to alert consumers to specific regional dangers posed by seafood, they alone are not sufficient to ensure that vulnerable subpopulations are made aware of the danger posed by raw molluscan shellfish. FDA estimates that one serving in every thousand of raw or partially cooked shellfish can cause illness. As two recent deaths in California demonstrate³⁷ and as Mr. Kilpatrick and Mr. Boynton can attest, the consequences of allowing vulnerable individuals to continue to eat raw shellfish are too serious. Therefore, a warning label should be required to alert high-risk consumers of the threat to their health from eating raw molluscan shellfish.

Public Health Surveillance Program

Greater emphasis must be placed on the reporting and collection of seafood-borne illness data. Currently, the CDC does not require the reporting of most seafood-borne illnesses and many state health departments adopt similar guidelines. A more thorough reporting system will make it possible for officials to more accurately assess risk from seafood-borne illnesses, develop strategies and policies to reduce risk and pinpoint areas where improvement of the inspection program is necessary.

CONCLUSION

The case studies presented in this report depict the human costs of ineffective regulation of the nation's seafood. The personal stories of the victims make a compelling case for Congress to take the quick and decisive action needed to address this serious health problem.

Both the Administration, which has opposed Congressional action, and Congress, which has failed to act on proposed legislation, bear responsibility for the needless suffering of individuals stricken with seafood-borne illness. It is the failure of federal authorities to take the steps necessary to safeguard the nation's seafood supply--steps that have been laid out for them in detail many times during the past four years--that has produced this nationwide public health disgrace.

The victims' stories illustrate more than the seriousness of the public health dangers posed by contaminated seafood. They also provide an eye-opening view of the diversity of seafood-borne illnesses that can strike consumers when federal regulatory programs fail to offer adequate protections. Even more striking is the fact that the victims documented in this report likely represent merely the tip of the iceberg. Over half of the individual cases reported in this study were never accounted for by the federal disease surveillance system and therefore never appeared in the federal statistics on the incidence of seafood-borne illness.

This failure of the disease reporting system illustrates the lack of attention paid to the incidence and implications of seafood-borne illness in this country by federal authorities. After all, it is the FDA, not consumer groups, that should routinely document and make public the kinds of case histories presented in this report.

Rather than document the problem, FDA officials routinely deny that a public health problem exists and repeatedly claim that they have the situation well under control. The

federal government's failure to effectively monitor seafood-borne illnesses makes it difficult for journalists and experts to critically evaluate federal agency claims about the safety of seafood and the impact of current federal programs. The same goes for FDA's limited monitoring of chemical contaminants in seafood.

This "see no evil, hear no evil, speak no evil" approach to regulation leaves the Administration unaccountable to the public and encourages it to deny the existence of this critical public health problem. But just as investigations by the National Academy of Sciences, *Consumer Reports* magazine and Cable News Network blew the cover off of FDA's denials about the problems posed by chemical contaminants in seafood, the victims' stories in this report demonstrate how current regulatory programs fail to prevent serious incidents of acute seafood-borne illness.

Decisive Congressional action to plug these holes in the seafood regulatory net is long overdue. Continued neglect will only serve the most narrowly defined, short-term economic objectives and will in the long run prove too costly to consumers, the food industry and the federal government alike. There will be more needless victims and personal tragedies. FDA's credibility as the protector of public health will be damaged. Public confidence in the safety of the seafood supply will be increasingly eroded. The public's perception that Congress is captured by privileged industry interests and is incapable of resolving the nation's urgent public health problems will be reinforced. Each of these long-term consequences, which the nation can ill-afford, can be prevented. It is now up to Congress and the Administration to take action.

ENDNOTES

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6. *Seafood Safety* at 95.
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8. *Id.* at 94.
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14. Correspondence with Mrs. Jean Mages, November 7, 1991.
15. *Seafood Safety* at 55.
16. *Id.*

17. *Id.* at 56.
18. Eastaugh at 1737.
19. *Id.*
20. *Id.*
21. Conversation with Dr. Ty Minton, June 10, 1992.
22. Eastaugh at 1738.
23. *Seafood Safety* at 89.
24. *Id.* at 91.
25. Eastaugh at 1737.
26. *Seafood Safety* 92-3.
27. Non-01 *vibrio cholerae* is a strain of naturally occurring marine bacteria associated with human disease. While non-01 *vibrio cholerae* may cause gastroenteritis in healthy persons, the illness can be life-threatening to people who are immunocompromised or have an underlying liver disease. It should be distinguished from *vibrio cholerae* 01, which may cause illness or death in otherwise healthy individuals.
28. *Id.* at 39, 42.
29. *Id.* at 39.
30. *Id.*
31. Conversation with Ms. Genese Dopson Smith, Mr. William Kilpatrick's attorney, October 14, 1991.
32. *Seafood Safety* at 39.
33. *Id.* at 42.
34. *Id.*
35. Eastaugh at 1735.
36. *Seafood Safety* at 50.
37. *Id.*

38. ABC's "20/20" transcript, June 22, 1990, at 3 [hereinafter 20/20 transcript].
39. Conversation with Ms. Maryanne Guichard, Washington Department of Health, November 18, 1991.
40. *Seafood Safety* at 101.
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45. *Id.* at 97, 99-100.
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Dine at Your Own Risk

The Failure of Local Agencies to Adopt and Enforce National Food Safety Standards for Restaurants

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EXECUTIVE SUMMARY

Hidden dangers lurk in restaurant food, dangers that can cause acute illness and sudden death. Harmful bacteria, viruses and parasites in ready-to-eat restaurant food cause several thousand deaths and millions of illnesses each year. Government data show that consumers are twice as likely to report getting sick from a food poisoning outbreak caused by restaurant food than from food prepared at home. And with more consumers eating away from home than ever before, the number of illnesses and deaths is likely to rise, unless restaurants and the state, city, and county agencies that regulate them improve systems for ensuring food safety.

Most food poisoning from restaurant-prepared food is easy to prevent. Simple steps, like checking cooking and refrigeration temperatures, and assuring proper handling, could greatly reduce foodborne illness from restaurant-prepared food. But in this examination of the standards used to regulate the restaurant industry by state and local agencies, the Center for Science in the Public Interest (CSPI) has documented gaping holes in the manner that restaurants are regulated around this country.

During an era when more and more responsibility is being shifted from the federal government to state and local governments, this examination of restaurant food safety makes two important findings: (1) despite the fact that the federal Food and Drug Administration (FDA) publishes national standards to guide states and localities in how best to regulate restaurants to prevent food poisoning, states and local governments often fail to adopt those national standards; and (2) even when the standards are adopted, inspection agencies have trouble enforcing them, due to infrequent inspections and funding deficiencies.

That is the bad news. But this report also documents the good news. More and more restaurants are setting and enforcing their own standards, using new systems of preventive controls called HACCP (which stands for Hazard Analysis and Critical Control Point) systems. These restaurant leaders are providing important examples for others in the industry. Federal, state, and local regulators should examine these systems, which may ultimately pave the way for mandatory adoption of HACCP systems in the restaurant industry.

KEY FINDINGS AND RECOMMENDATIONS

In a survey of 45 state and local government agencies that conduct inspections of restaurants, CSPI found that a large majority of agencies are not following FDA's national standards for restaurants (the "Food Code"). The worst agencies CSPI

surveyed included the ones in San Francisco, California; Dallas, Texas; Detroit, Michigan; and the state of Delaware. Concord, New Hampshire, and the state of Rhode Island were the two best agencies CSPI surveyed.

- Only 16% of the agencies surveyed enforce the FDA Food Code recommended cooking temperatures for pork, eggs, fish, and poultry, and only 64% require hamburgers to be cooked to 155°F, the temperature necessary for *E. coli* O157:H7 to be destroyed in 15 seconds.
- Only 11% of the agencies require refrigeration of food at the temperature recommended by FDA.
- Only 20% of the agencies follow Food Code temperature recommendations for cooling cooked food.
- Less than half of the agencies inspect restaurants twice a year.*
- Only 16% of the agencies require consumer warnings for raw food, like shellfish, and undercooked food, like rare hamburgers.

Even where states and localities are using the most current version of the FDA Food Code, inspectors complain that their work is compromised by lack of funding and inadequate inspection tools. Ultimately, restaurants themselves will have to provide greater assurance to both their customers and the government regulators that they are serving the safest possible meals.

The nationwide publicity that followed the outbreak of a deadly strain of *E. coli* bacteria traced to fast-food hamburgers in 1993 and publicity regarding

the safety of certain products such as seafood has provided the incentive for many restaurants to test new systems to improve their food safety performance. Preventive HACCP controls, coupled with laboratory testing, are being used in several national restaurant chains.

Adoption of the following recommendations would greatly improve the safety of food served in restaurants:

- All state and local governments should incorporate the 1995 FDA Food Code's food safety standards into their laws governing inspection, and should update their laws whenever the Food Code is updated.
- State and local governments should mandate that restaurants utilize HACCP systems to improve the safety of the meals they serve. Local health authorities should assist restaurants in setting up and monitoring HACCP plans, and should verify that HACCP plans are working by conducting periodic laboratory testing of food and equipment samples taken from restaurants. Inspectors should have the proper equipment to measure cooking temperatures of food during inspections.
- State and local governments should make restaurant food safety a higher budgetary priority and should ensure that local inspection agencies have sufficient funds to carry out their functions.

* Only 33 of the 46 agencies provided complete data on the numbers of inspections they perform.

- State and local governments should work with restaurants and restaurant trade associations to develop food safety recognition programs for restaurants. Eligible restaurants should be those that have consistently maintained safe operations and that have instituted HACCP systems, including comprehensive, ongoing training programs for their employees. Such restaurants could be recognized by the awarding of a “seal of approval” that could be displayed as a window decal and used in advertising.
- FDA should revise the Food Code to include model inspection forms that focus on the most critical violations that affect food safety, rather than on more technical violations. The model forms, used by many jurisdictions, should be designed to help inspectors effectively target violations that jeopardize public health during their limited time in each restaurant.
- The FDA Food Code should include generic HACCP models for different types of restaurants, with guidance to local health agencies for assisting restaurants in setting up the plans.
- Even if not required to do so by law, all restaurants should establish HACCP plans to identify and control the risks of foodborne illness in their operations.
- Since harmful pathogens frequently contaminate the food supply, particularly seafood, meat, poultry, and eggs, HACCP plans should contain provisions for restaurants to monitor the quality of products they receive from suppliers, including the use of temperature monitoring devices during shipping and laboratory testing of suppliers’ products. Restaurant HACCP plans should require that suppliers implement their own HACCP plans to ensure the safety of food from the farm through the processing and shipping stages.
- Food-service workers and their supervisors should be required to undergo training in food safety, as at least nine jurisdictions already require. State and local health agencies should mandate that restaurants provide such training, or alternatively should offer courses for workers funded by restaurants.
- To encourage the adoption of uniform standards, Congress should allocate money for increased restaurant inspection and enforcement to states that adopt the FDA Food Code’s food safety and inspection standards. The money should not be taken from the existing budgets of federal food safety agencies.
- On both the state and federal levels, additional funding should be allocated for epidemiological studies of foodborne illness.
- The U.S. Department of Agriculture (USDA) and FDA should step up their efforts to ensure that seafood, meat, poultry, and eggs are as free from harmful bacteria and other contaminants as possible.

INTRODUCTION

Restaurant customers have a right to expect that the food they eat will not harm them. Yet, customers have no way to control what goes on in restaurant kitchens. They depend on restaurants to follow safe standards of food handling, and on local inspection agencies to enforce those standards. But each year, many millions of illnesses and thousands of deaths are linked to food prepared in the nation's restaurants, delicatessens, and cafeterias, a fact which shows that inspection agencies and restaurants often let customers down.

The best available national data show that, between 1983 and 1992, 42% of all reported food-poisoning outbreaks* were traced to food eaten in restaurants, delicatessens, and cafeterias. In comparison, only 21% of the food-poisoning outbreaks were attributed to food eaten at home.¹

Although there is no official estimate of how many of the 6.5 million to 33 million food poisonings a year are caused by food eaten in restaurants, there are likely millions of such illnesses, all of which could be prevented by better food handling in restaurants and better enforcement of national food safety standards.²

Both industry and government officials agree that the food safety problems linked to restaurants are substantial. In 1995, a General Mills Restaurants executive, Ron Magruder, acknowledged that as many as 4,500 restaurant patrons die each year from foodborne illness. Mr. Magruder

stated, "I find that shocking," adding that the industry "needs to do a better job" in addressing the problem.³

"Whatever the size of the problem, it's big, not small, and whatever percentage of the problem is attributable to restaurants, it's bigger than it should be," said Morris Potter, Assistant Director for Foodborne Disease at the Centers for Disease Control and Prevention (CDC). "With better enforcement of food safety standards, many food poisonings from restaurants could be prevented."⁴

According to a CSPI survey of state and county restaurant inspection agencies described in this report, many inspection agencies do not enforce nationally accepted standards to ensure food safety. Even though the FDA Food Code provides a set of food safety standards for restaurants, the majority of surveyed state and local jurisdictions either use outdated versions of the Food Code or have never adopted key parts of it. Agencies with the most outdated standards include those in Detroit, San Francisco, Dallas, and the state of Delaware. The two agencies with the most up-to-date standards were Concord, New Hampshire and the state of Rhode Island.

Many state and local governments also fail to provide inspection agencies with adequate budgets. Underfunding of restaurant inspection agencies prohibits them from properly training staff and providing needed equipment, hampering the agencies' effectiveness, according to Potter of CDC.

* An outbreak is generally defined as two or more people made sick by the same food.

RESTAURANT FOOD CAUSES TOO MANY CASES OF FOOD POISONING

Eating Out Can Be Hazardous To Your Health

Americans are eating more of their meals in restaurants. The latest statistics available show that in 1993, consumers spent a record 46% of their food dollar on food eaten away from home, up from 39% in 1980.⁵

The primary reason cited by consumers for eating away from home is that they do not have time to cook.⁶ As greater numbers of adults are fully employed outside the home, consumers increasingly rely upon the convenience of restaurant or delicatessen food to replace or supplement home-prepared food. But consumers may not realize that food served in a restaurant is at least as likely to carry the risk of foodborne illness and death as food prepared in the home.

Precise figures on the extent of food poisoning attributable to restaurants are not available because there is no comprehensive national system to track food poisonings. The best available data come from CDC, which collects food poisoning outbreak data from state and local health departments. CDC data covering the years 1983 through 1992, the most recent data available, show that 42% of all reported outbreaks were traced to food eaten in restaurants, delicatessens, and cafeterias, compared to 21% for food eaten at home.⁷

Although many public health officials believe that food poisoning from food prepared at home may be a larger share of the food poisoning problem than CDC data indicate, they agree that restaurant food poisoning outbreaks are more likely to affect

a larger number of people. Better food handling practices in restaurants coupled with adoption of national standards and better enforcement by state and local regulators could greatly reduce food poisonings from food prepared in restaurants.

One food safety mistake in a restaurant kitchen can sicken large numbers of people, sometimes hundreds at a time. Some reasons for large restaurant-caused outbreaks include:

- Restaurants often prepare several different types of food in the same kitchen at the same time, so that one food containing harmful bacteria can contaminate many other foods unless handled carefully.
- Restaurants handle large quantities of food at a time, making it harder to keep food at temperatures that prevent growth of bacteria.
- One food handler who fails to practice good hygiene, such as proper hand washing, can contaminate food that is then served to many people.

Highlighted below are just some of the larger outbreaks of restaurant food poisoning in recent years:

- Massachusetts, June 1996. Food contaminated with *Salmonella* that was served in a Wendy's restaurant in suburban Boston sickened 38

people and may have contributed to a death.⁸ Investigators determined that the outbreak was caused by employees who did not wash their hands before handling food.

- Idaho, September 1995. At least 11 cases of illness due to *E. coli* O157:H7 were traced to food eaten in a Chili's restaurant in Boise.⁹ The primary source of the *E. coli* O157:H7 bacteria is beef, but in this outbreak, authorities believe raw beef carrying the bacteria probably cross-contaminated other food served in the restaurant.
- Florida, August 1995. *Salmonella newport* bacteria sickened over 850 people in the largest outbreak of foodborne illness in Florida history.¹⁰ Health officials who investigated the outbreak believe that *Salmonella* bacteria in chicken cross-contaminated several other foods served at Margarita y Amigas restaurant in West Palm Beach, at least in part because workers used the same cutting board for raw meat as for vegetables.¹¹
- Utah, January 1995. An outbreak of 95 cases of hepatitis A was traced by the local health department to an employee of a Taco Bell restaurant in Salt Lake City.¹² The hepatitis A virus is carried in human fecal matter and is spread when food handlers do not wash their hands thoroughly.
- Washington, D.C., August 1994. Hollandaise sauce contaminated with *Salmonella* served at a brunch at a hotel sickened 56 people, 20 of whom were hospitalized.¹³

According to investigators, the sauce was prepared from raw eggs and heated over a hot water bath. It was then held for nine hours at a temperature at least 20 degrees lower than that recommended by the FDA Food Code.

- Georgia, October 1993. A botulism poisoning outbreak killed a customer of a delicatessen in a small south Georgia town and sickened seven others.¹⁴ Their illnesses were traced by CDC officials to canned cheese sauce, which had been left opened and unrefrigerated for eight days, served on baked potatoes stuffed with barbecued meat. Health officials said proper refrigeration of the sauce could have prevented the outbreak.
- Illinois, June 1993. A Mexican restaurant in a Chicago suburb served *Salmonella*-tainted food that sent 25 people to the hospital and sickened 16 others. County investigators attributed the outbreak to prepared food not being held at hot enough temperatures, and to poor food handler hygiene.¹⁵
- Oregon, March 1993. In Grant's Pass and North Bend, 48 people were sickened by *E. coli* O157:H7 bacteria in mayonnaise served at Sizzler's restaurants.¹⁶ According to data reported to CDC, the mayonnaise was cross-contaminated by a food, mostly likely raw or insufficiently cooked ground beef, that contained *E. coli* O157:H7 bacteria. An additional 50 cases of illness caused by *E. coli* O157:H7 bacteria in food served in Sizzler's restaurants in

Oregon and Washington were reported to CDC in 1993.¹⁷

- The Western U.S., December 1992 to January 1993. The largest *E. coli* O157:H7 outbreak in the U.S. occurred in Washington, Idaho, Nevada, and California and was linked to contaminated hamburgers

served at Jack in the Box restaurants.¹⁸ At least 700 cases of foodborne illness were reported.¹⁹ Nearly 100 of the victims developed hemolytic uremic syndrome, a serious complication resulting from *E. coli* O157:H7 infection, and four children died, the oldest just six years old.²⁰

Food Poisoning Is a Widespread and Costly Problem

Those outbreaks are just the tip of a deadly iceberg. Experts agree that foodborne illness is seriously underreported by CDC.²¹ First, CDC maintains data only for outbreaks and not for individual cases.²² Second, whether CDC ever hears about an outbreak depends on many factors, including whether the victims ever seek medical attention; whether patients and their doctors recognize the cause of the illness; whether doctors are motivated to contact the local health department; and whether area laboratories have the resources to identify the pathogen.²³ One public health official estimates that only one of every 250 cases of foodborne disease is eventually reported to a local or state health department.²⁴ Finally, some states do not require reporting of key foodborne diseases and may not be vigilant about reporting to CDC. In 1994, twelve states had no surveillance staff specifically assigned to monitoring foodborne illness, meaning that outbreaks are not reported routinely from those states.²⁵

Foodborne illness is a major public health risk. Particularly in children, the elderly, and those with weak immune systems, foodborne pathogens can kill or cause long-term health effects, including hemolytic-uremic syndrome and reactive arthritis. For thousands more people, foodborne illness causes personal discomfort and lost days at work.

Foodborne illness is also costly. The federal government has estimated the cost of illness in 1993 from just seven pathogens (the bacteria *Campylobacter*, *Salmonella*, *E. coli* O157:H7, *Clostridium perfringens*, *Staphylococcus aureus*, and *Listeria*, and the protozoan *Toxoplasma gondii*) at \$5 billion to \$9 billion.²⁶ This estimate does not include any illnesses caused by other bacteria, viruses, or toxins commonly found in food.

HOW RESTAURANT FOOD CAN MAKE YOU SICK

Pathogens that cause food poisoning, such as bacteria and viruses, can show up in restaurant food served to customers as a result of food handling mistakes like inadequate cooking, cross-contamination in

the kitchen, or improper cooling. At every stage of food preparation, from purchasing food from suppliers to serving customers, restaurants need to be aware of potential pathogens in food.

How Restaurants Allow Pathogens to Spread and Grow

Although the causes of foodborne illness are well understood and often readily preventable, restaurants frequently handle food in ways that can sicken people. According to a five-year study of the trends in reported foodborne illness outbreaks, the top four reported causes of food poisoning are (1) holding or storing food at improper temperatures, reported in 59% of outbreaks; (2) poor personal hygiene of food handlers, reported in 36% of outbreaks; (3) inadequate cooking of food, cited in 28% of outbreaks; and (4) contaminated equipment, cited in 16% of outbreaks.²⁷

Areas of risk exist throughout a typical restaurant's operation, starting with the purchase of raw food from suppliers. Bacteria that exist in raw food can multiply and produce toxins if the food is inadequately refrigerated during shipping and handling, even before it reaches the restaurant.

Once inside the restaurant, raw poultry, meat, and seafood must be properly refrigerated to prevent growth of harmful pathogens and must be handled carefully to

prevent cross-contamination of other food. Restaurant workers can also contaminate both raw and cooked food they handle if they do not wash their hands thoroughly and frequently.

Cooking food is another area of risk. Undercooked meat, poultry, and eggs can harbor enough bacteria to sicken some customers. Frozen meat that has not been completely thawed before cooking is often accidentally undercooked.

Even properly cooked food can become dangerous if restaurants do not carefully monitor the temperatures at which the food is kept. While adequate cooking kills most bacteria in food, some bacteria form spores that can survive even very high temperatures and re-generate into bacteria. Cooked food may also be re-contaminated by bacteria due to careless handling. Bacteria can multiply in warm, cooked food when the food is not cooled rapidly enough. Likewise, they can multiply in food held in warming pans if the temperature is not high enough to kill them.

Pathogens in Raw Food

Harmful bacteria, including *Salmonella* and *E. coli* O157:H7, accounted for 74% of the reported restaurant-associated food poisoning outbreaks between 1988 and 1992 where the cause was known.²⁸ CDC reported that *Salmonella* caused 60% of all reported restaurant outbreaks where the cause was known.²⁹ (See Table I.)

Salmonella bacteria contaminate an estimated 20% of raw broiler chicken carcasses.³⁰ *Salmonella enteritidis*, the strain of *Salmonella* most likely to contaminate eggs, caused between 200,000 and 1,000,000 illnesses in 1994, the last year for which such data are available.³¹ Salmonellosis symptoms, which include nausea, abdominal cramps, diarrhea, fever,

and headache, usually appear within six to 48 hours after eating.³² *Salmonella* causes bloodstream infections and long-term complications, such as reactive arthritis.³³ In the very old, the very young, and the immuno-compromised, infection can lead to death. Some standard egg cooking practices, including frying eggs "sunny side up," are often not sufficient to kill all the *Salmonella* that may be present in raw eggs.³⁴

E. coli O157:H7, which has been linked to beef and other foods, sickens an estimated 21,000 people annually and kills at least 450.³⁵ It is present in beef only when the animals' intestinal contents or manure are permitted to contaminate the muscle

Table I. Sources of Reported Restaurant Outbreaks with Confirmed Cause, 1988-1992

Cause	Percent of Outbreaks
<i>Salmonella</i>	60%
Scombrototoxin	15%
Hepatitis A	7%
<i>Staphylococcus aureus</i>	3%
<i>Clostridium perfringens</i>	3%
<i>Bacillus cereus</i>	3%
<i>Campylobacter</i>	2%
<i>Shigella</i>	2%
Ciguatoxin	2%

Source: CDC, "Surveillance for Foodborne-Disease Outbreaks-United States, 1988-1992," *Morbidity and Mortality Weekly Report*, Vol. 45, No. SS-5 (1996), pp. 26-30.

meat during slaughter.³⁶ Infection from *E. coli* O157:H7 can cause severe abdominal cramps, bloody diarrhea, and hemolytic-uremic syndrome, which can result in kidney failure and death.³⁷

Seafood, too, can carry dangerous pathogens. Scombroid fish poisoning, which causes flushing and gastrointestinal symptoms, was responsible for 15% of all reported restaurant outbreaks between 1988 and 1992 where the cause was known.³⁸ Scombroid fish poisoning is caused by certain types of fish, including fresh tuna, mackerel, and mahi mahi, in which decomposition of fish tissue by bacteria

results in production of histamine, a toxin. Scombroid fish poisoning occurs when fish are not properly refrigerated, allowing bacteria to multiply.³⁹

People with liver damage or weakened immune systems who eat raw oysters or other shellfish containing the bacteria *Vibrio vulnificus* and *Vibrio cholerae* can become seriously ill and die. These two *Vibrio* bacteria can cause bloodstream infections and death. Along with *Vibrio parahaemolyticus*, they are responsible for an estimated 42,000 illnesses each year.⁴⁰

Pathogens Spread By Poor Handling Practices and Poor Hygiene

Pathogens in raw food can be spread around the kitchen if workers do not handle raw food properly. *Salmonella* in raw poultry juices or *E. coli* O157:H7 in raw beef juices can cross-contaminate other foods. Cross-contamination occurs when pathogens are spread from a contaminated food to other food via equipment, utensils, cleaning sponges, towels, or a worker's hands.⁴¹

Most pathogens enter restaurant food through raw food or cross-contamination. However, three pathogens come primarily from infected food workers: hepatitis A virus and *Shigella* and *Staphylococcus aureus* bacteria.⁴² Hepatitis A and *Shigella* are carried in human fecal matter. The illnesses they cause can be prevented by proper hand washing.⁴³

The hepatitis A virus causes 7% of all reported restaurant-related outbreaks

where the cause is known, according to CDC data.⁴⁴ The symptoms include nausea, vomiting, fever, and jaundice, while severe cases can cause liver damage and death.⁴⁵

Shigella causes about 2% of reported foodborne illness in restaurants where the cause is known. The illness can show up as late as one week after eating, and causes abdominal cramps, fever, and diarrhea.⁴⁶

Food service workers who carry certain strains of *Staphylococcus aureus* bacteria in their skin or nostrils can contaminate food, which, if it is left too long at room temperature, can then cause staphylococcal food poisoning.⁴⁷ Staphylococcal food poisoning, with symptoms of diarrhea, vomiting, nausea, and abdominal pain, caused 3% of reported restaurant outbreaks between 1988 and 1992.⁴⁸

Pathogens in Cooked Food

Pathogens may be present in cooked food that has not been heated to sufficient temperatures during cooking, and in food that has been cross-contaminated after cooking. Those pathogens can multiply rapidly if the cooked food is not kept at proper temperature. Both *Salmonella* and *Clostridium perfringens* bacteria, for example, grow in cooked food that is not

kept hot or cool enough. *Clostridium perfringens* can grow better than most bacteria at temperatures as high as 120°F. *Clostridium perfringens* caused 3% of reported restaurant outbreaks between 1988 and 1992 where the cause was known.⁴⁹ Its symptoms are abdominal pain, diarrhea, nausea, and vomiting, and can be more serious in elderly or debilitated people.⁵⁰

ENFORCING FOOD SAFETY STANDARDS

Restaurants should serve food that is safe to eat and is prepared under safe and sanitary conditions. Because consumers have no control over how the food they eat will be prepared, they rely upon tough standards enforced during frequent inspections by government agencies. But in too many cases, restaurants are not serving safe food, and state and local inspections are not stopping food poisoning outbreaks caused by restaurant food.

Responsibility for regulating and inspecting restaurants and other retail food establishments is distributed among an estimated 3,000 state and local agencies.⁵¹ Responsibility for restaurant inspections generally lies at the county or city level, although several states, including Hawaii, Vermont, Rhode Island, and Delaware, handle inspections through a statewide agency. Despite the fact that generally accepted national standards exist, each state or locality has its own laws governing restaurant safety, and the laws vary widely.

FDA's Food Code: A National Food Safety Standard

National standards for restaurant safety are contained in the Food Code, published by the Food and Drug Administration (FDA). FDA does not have the legal authority to impose these standards on state and local jurisdictions. Because a national food safety standard guarantees people around the country the same level of safety, FDA encourages state and local governments to adopt the Food Code.

Even though the Food Code is not law, it represents expert consensus on scientific standards for safe food and provides guidance to agencies around the country. FDA created the Food Code in consultation with representatives from many scientific and technical authorities representing academia, government, and industry.⁵²

The Food Code is updated every two years to reflect increased understanding of foodborne illness and was most recently updated in 1995. Even though every state and many local jurisdictions have adopted some edition of the Food Code, many do not follow the standards set out in either the 1993 or the 1995 version.⁵³ For example, the state of Hawaii uses the 1962 version, and Linn County, Iowa, uses the 1976 version.⁵⁴

The Food Code includes temperature standards for cooking, cooling, refrigerating, reheating, and holding food. It recommends that restaurants give warnings to customers about the dangers of eating raw or undercooked food. It also recommends that inspectors visit restaurants every six months and immediately shut down restaurants with conditions that pose an imminent health hazard.

Survey Of Local Inspection Agencies

Between January and March of 1996, CSPI conducted a survey to determine whether state and local agencies are enforcing key food safety standards in the FDA Food Code when conducting restaurant inspections. The Food Code contains dozens of standards ranging from food storage to restaurant plumbing and ventilation. For the survey, CSPI selected 12 standards that are crucial to customer health and safety, including food cooking and refrigeration temperatures, frequency of

inspections, and consumer warnings for raw foods.

CSPI surveyed a sample of 45 agencies from across the country, representing a mixture of urban and rural localities from each of six geographic regions: the Northeast, the Mid-Atlantic, the Southeast, the Midwest, the Southwest, and the West. Surveys were conducted by telephone or telecopier with a public health official responsible for food inspection. (See Table II on p. 32.)

Food Safety Standards That Many Inspection Agencies Do Not Follow

None of the state and local agencies surveyed are following all of FDA's Food Code recommendations. Many agencies are not requiring restaurants to cook food at temperatures that kill bacteria and to cool and refrigerate it at temperatures that keep bacteria from multiplying. Most agencies are not requiring restaurants to warn consumers of the dangers of eating potentially dangerous raw foods, such as shellfish. Many agencies are not inspecting restaurants every six months. Key findings include:

- Only 16% of the agencies surveyed enforce the FDA Food Code recommended cooking temperatures for pork, eggs, fish, and poultry, and only 64% require hamburgers to be cooked to 155°F, the temperature

necessary for *E. coli* O157:H7 to be destroyed in 15 seconds.

- Only 11% of the agencies require refrigeration of food at the temperature recommended by FDA.
- Only 20% of the agencies follow Food Code temperature recommendations for cooling cooked food.
- Less than half of the agencies who responded inspect restaurants twice a year.
- Only 16% of the agencies require consumer warnings for raw food, like shellfish, and undercooked food, like rare hamburgers.

Insuring Adequate Cooking of Food

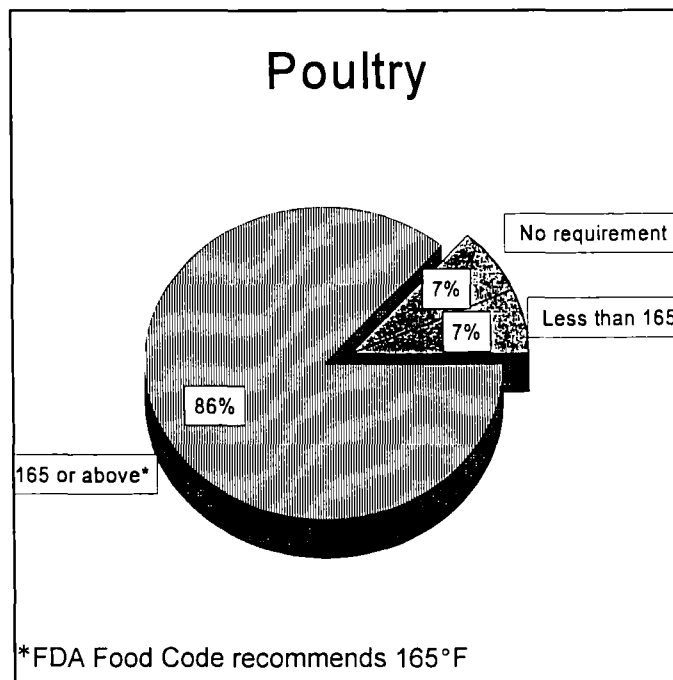
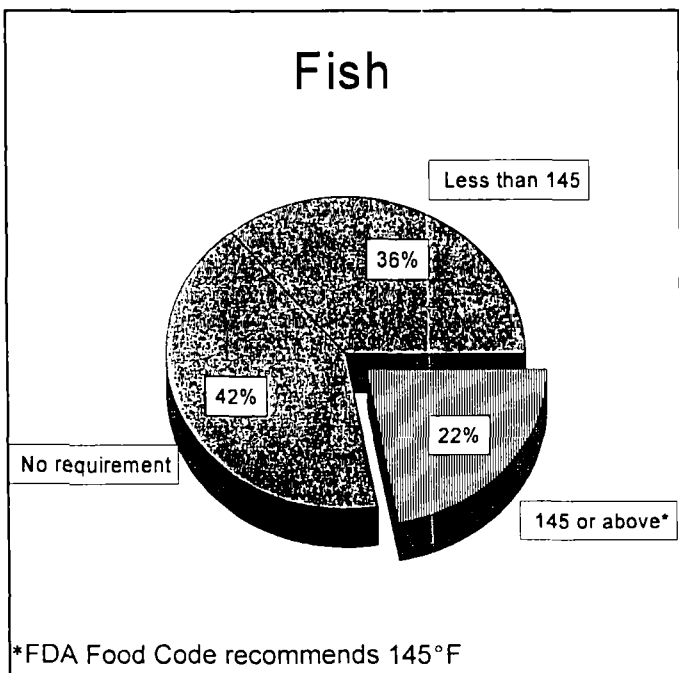
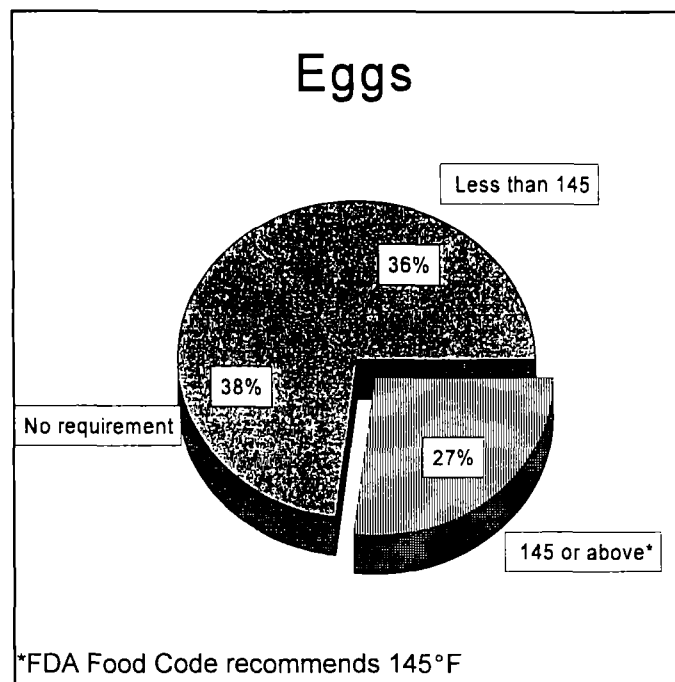
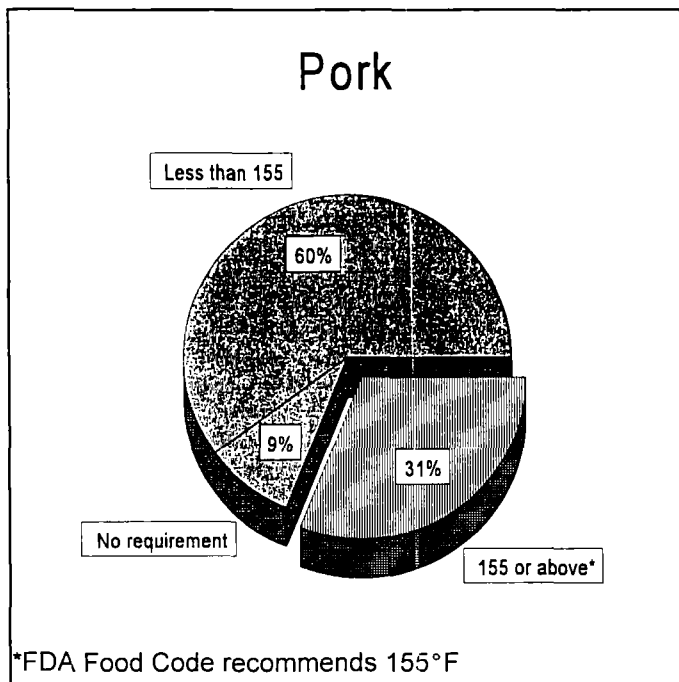
Cooking Temperature Requirements for Pork, Eggs, Fish, and Poultry

Because inadequate cooking is a leading cause of foodborne illness, the FDA Food Code recommends specific cooking temperatures for raw pork, eggs, fish and poultry. Poultry should be heated to 165°F; pork and processed fish should be heated to 155°F; and whole fish should be heated to 145°F.⁵⁵ Eggs cooked in response to a customer's order for immediate service should also be heated to 145°F.⁵⁶

CSPI asked the inspection agencies about their cooking temperature requirements for pork, eggs, fish, and poultry. Only 16% of responding agencies follow the Food Code's cooking temperature recommendations for all four foods. (See Figure I on p. 17.)

Most of the other 84% of agencies have cooking temperature standards for at least some of those foods, but the required temperatures often may not be high enough to kill bacteria that can cause illness or death. For pork, 60% of responding agencies have cooking temperatures lower than the recommended temperature of 155°F, and 9% have no standard at all. Pork can contain *Trichinella spiralis*, a parasite that causes serious illness, and the bacteria *Salmonella* and *Campylobacter*, which can be killed only by thorough cooking. For eggs, 36% of localities have lower-than-recommended cooking temperatures, and 38% have no standard at all. For fish, 36% have lower-than-recommended cooking temperatures, and 42% have no standard at all. For poultry, 86% follow the FDA recommended temperatures, while 7% do not have a standard. Three health departments, including two in California, have no required cooking temperatures in their codes.

Figure I. Cooking Temperature Requirements for Pork, Eggs, Fish, and Poultry



Cooking Temperature Requirements for Hamburger

In order to kill deadly *E. coli* O157:H7 bacteria that may be present in ground beef, the FDA Food Code recommends that hamburgers be cooked at

an internal temperature of 155°F for 15 seconds.* Despite the numerous outbreaks from this strain of *E. coli*, 20% of the agencies surveyed fail to apply this standard and 16% have no temperature requirement at all. (See Figure II on p. 19.)

Refrigerating Food at Proper Temperature

The FDA Food Code recommends a cold storage temperature of 41°F for all raw and cooked food that needs to be refrigerated.⁵⁷ Only 11% of inspection agencies surveyed require refrigeration of potentially hazardous food to 41°F. The other 89% require a cold storage temperature at or below 45°F.⁵⁸ (See Figure III on p. 19.)

The dangers of inadequate refrigeration are well known. Certain types of *Listeria* and *Clostridium botulinum* continue to multiply slowly in foods at temperatures of 45°F. Those pathogens must be chilled to 41°F to stop their growth.⁵⁹

Cooling Previously Cooked Food

The 1995 FDA Food Code recommends that cooked, potentially hazardous food be cooled from 140°F to 70°F within two hours and from 70°F to 41°F within four hours.⁶⁰ Only 20% of state and local health departments surveyed enforce this standard. (See Figure IV on p. 19.) Most require a low temperature of 45°F, not the 41°F necessary to prevent some pathogens from multiplying.

Rapid cooling is best done by placing food into shallow containers and then placing the containers in a rapid chill device such as an ice bath. Using shallow containers is important if the food is to be adequately cooled. Food heaped higher than four inches generally will not cool rapidly enough in a refrigerator.⁶¹

* Specifically, the FDA temperature and time specification for cooking hamburger is:

- a) 155° F for 15 seconds - or -
- b) 150° F for one minute - or -
- c) 145° F for three minutes. (*FDA Food Code*, (1995), §§ 3-401.11(2); 3-401.12.)

This report only highlights respondents who have a cooking temperature requirement of 155° F, because it is questionable whether the lower cooking temperature standards, with their required longer cooking times, can be adequately enforced in fast-food restaurants.

Figure II. Cooking Temperature Requirement for Hamburger

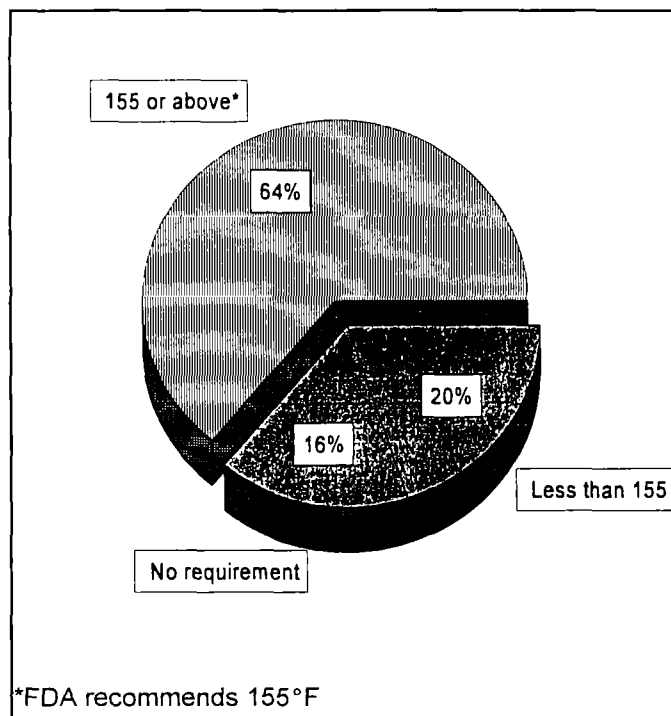


Figure III. Refrigeration Temperature Requirement

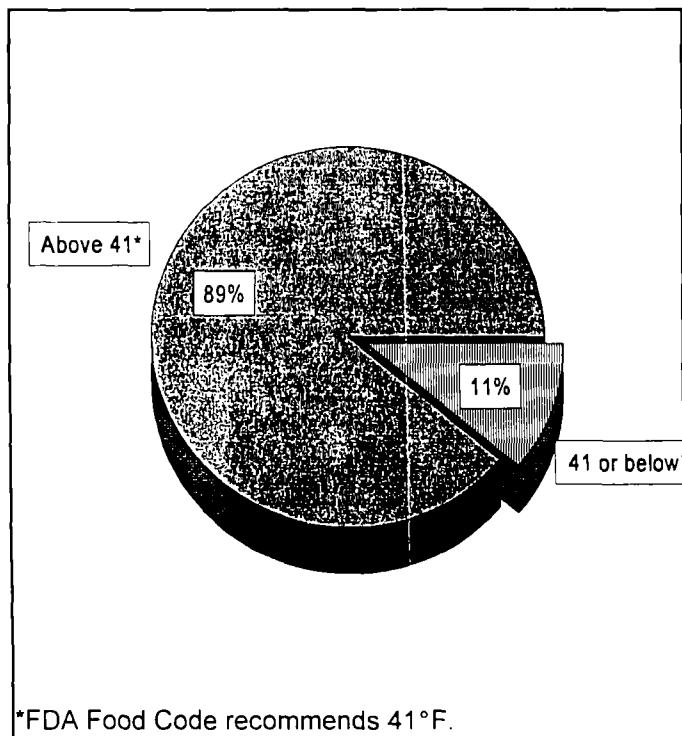
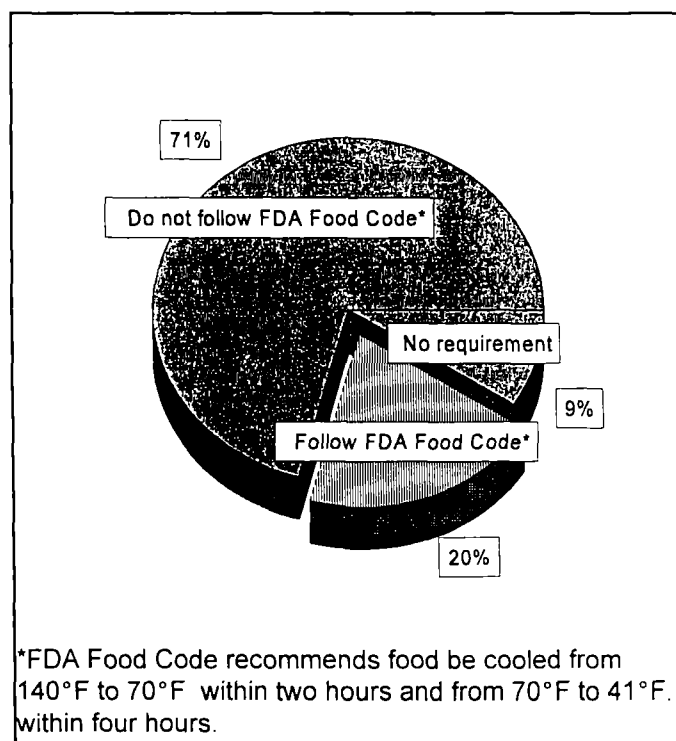


Figure IV. Cooling Temperature Requirement



Inspecting Restaurants Frequently and Thoroughly

Frequency of Inspections

The FDA Food Code recommends that restaurants be inspected at least once every six months.⁶² Sixty-seven percent of the 33 surveyed agencies that gave CSPI inspection data stated that they follow or exceed this recommendation, while 33% said they inspect less than twice a year.* (See Figure V on p. 21.)

To test the accuracy of those responses, CSPI asked respondents for data on the number of restaurants in their jurisdiction as well as the actual number of restaurant inspections performed in 1994. Based on those numbers, only 48%, not 67%, of the agencies inspected restaurants twice or more a year.⁶³ (See Figure VI on p. 21.) In other words, 22 agencies told CSPI they inspect more than twice a year, but based on their own 1994 data, only 16 were actually doing so.

When agencies do not inspect restaurants frequently enough, violations could go unchecked for months, increasing the risk of food poisoning.

Average Length of Inspections

The average length of time agencies reported spending on an inspection was one hour and 14 minutes. Officials in Los Angeles and San Francisco, California,

reported spending an average of just under 40 minutes on each inspection; the agency in Las Vegas, Nevada, spends about 35 minutes; and the agency in Hartford, Connecticut, spends only 20 minutes unless it has received a complaint about a restaurant. In contrast, inspections in Baltimore, Maryland, average three hours in length, and in the state of Rhode Island, two-and-a-half hours.

The FDA Food Code does not specify the amount of time an inspection should take. However, during an inspection, an inspector should check and document food temperatures, cooling procedures, storage facilities, cleanliness, staff hygiene and other potential areas of risk. Food safety could be compromised if inspections are not thorough.

Laboratory Testing

At least three of the 45 inspection agencies surveyed send food samples taken from restaurants during routine inspections to a laboratory to be tested for the presence of foodborne pathogens. Budget constraints were cited by some agencies as the primary reason for not doing random laboratory testing. However, many agencies emphasized that lab testing was done to confirm a suspicion of a food poisoning outbreak or when investigating a complaint against a food service establishment.

* Two of the agencies (Erie County, New York, and Jefferson County, Alabama) reported a range of numbers of inspections per year, based on perceived risk of type of establishment, in which the lowest number of inspections was one per year. These two agencies were excluded from the calculations in this section. Ten other agencies were excluded because they did not provide data for their 1994 inspections.

Figure V. Reported Frequency of Inspections Per Restaurant in 1994.

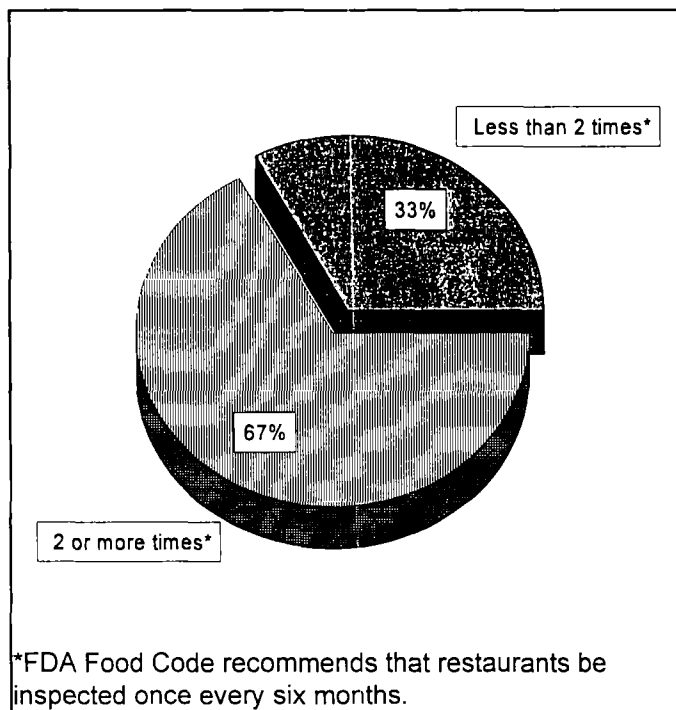
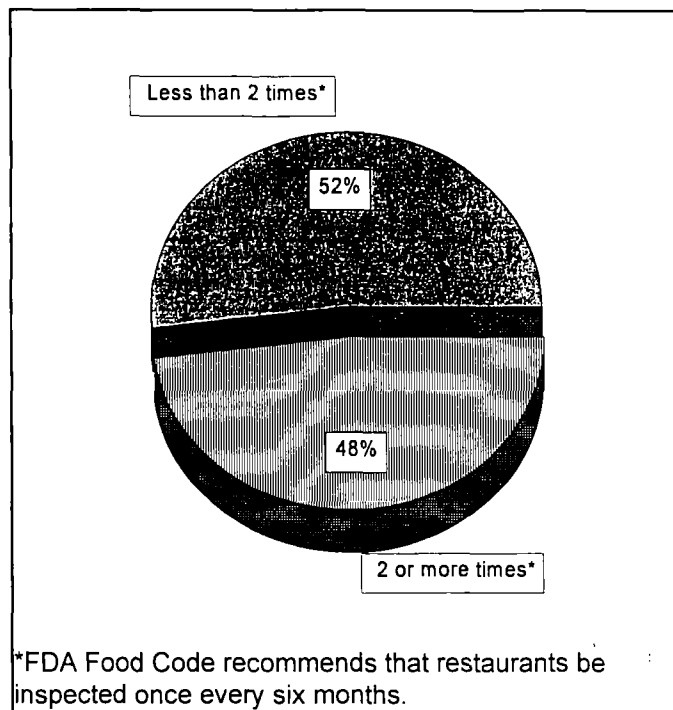


Figure VI. Actual Frequency of Inspections Per Restaurant in 1994.



Warning Consumers About Risky Food

Raw oysters and other shellfish can carry the deadly *Vibrio* bacteria. Rare ground beef can harbor *E. coli* O157:H7 and undercooked eggs can contain *Salmonella*. Yet, many vulnerable consumers are not informed of these health hazards and continue to eat raw or undercooked animal food.

According to the FDA Food Code, restaurants should post warning notices on menus, table signs, or elsewhere in the restaurant, stating the danger to vulnerable consumers of eating raw or undercooked animal food such as meat or shellfish.⁶⁴ Only 16% of the 45 inspection agencies

surveyed require restaurants and other food service establishments to post a consumer advisory. The agency in Tampa, Florida, follows Florida state law requiring a consumer advisory only for raw oysters.

Visits to restaurants in some of the jurisdictions that require such advisories showed that the advisories are often not in place. A seafood restaurant in San Francisco, California, that serves raw oysters; a sushi restaurant in Los Angeles County, California; and a restaurant that serves raw oysters in Orlando, Florida, all failed to provide any kind of consumer advisory. Of the four restaurants visited,

only an oyster bar in Providence, Rhode Island, provided warnings of the hazards of eating raw food.

The raw oyster advisory in Florida was implemented following numerous

deaths in that state from the consumption of raw shellfish. However, a 1995 University of Florida study showed that only 66% of Florida restaurants were actually complying with the consumer advisory law.⁶⁵

Food Safety Standards That Most Inspection Agencies Follow

Even though most of the agencies surveyed apply the FDA Food Code standards set out below, inspection agencies cannot ensure that restaurants follow the standards at all times. Restaurants must take

responsibility for enforcing food safety standards, including regularly monitoring the temperature of food being held or reheated and ensuring that employees are trained in proper hygiene.

Reheating Previously Cooked Food

The FDA Food Code recommends that previously cooked food be reheated to 165°F for 15 seconds before serving.⁶⁶ Of the agencies surveyed, only five do not comply. Four have a reheating temperature requirement below 165°F, while Clark County, Nevada, where Las Vegas is located, has no reheating temperature requirement at all.

Adequate reheating temperatures can be as important as initial cooking temperatures, especially if previously cooked foods were not sufficiently cooked

or were contaminated after cooking. If those previously cooked foods were stored at improper temperatures, any pathogens they might contain could multiply to dangerous levels. For example, a raw chicken might have from ten to 100 *Salmonella* bacteria spread over its carcass. If some of the bacteria survive cooking or the chicken is contaminated after cooking, those bacteria could multiply to millions by the time the cooked chicken is reheated.⁶⁷ Thorough reheating is necessary to kill any bacteria that may be present in the chicken.

Hot Holding of Food

The FDA Food Code recommends that hot food be held at a temperature of 140° F or higher.⁶⁸ Only one of the surveyed agencies, Charleston County, South Carolina, has a temperature below this standard. The other agencies comply with the Food Code's standard.

Hot foods that are not kept warm enough can present a health hazard for consumers. If the temperature of the warming device is not high enough, illness-causing bacteria can multiply in food. Food that is allowed to remain in steam tables or other heating pans, or in ovens set at low temperatures, is often implicated in food poisoning outbreaks.⁶⁹

In steam tables and other heating pans, such as those used in buffets, the food closest to the top is the coolest, while for food in ovens, the geometric center of the food is the coolest. These areas of the food might not be hot enough to prevent bacterial

growth. Lids can help keep food hot inside the pans.⁷⁰ Alternatively, food held at hot temperatures without lids should be stirred regularly to decrease the risk of bacterial growth in the coolest parts of the food.⁷¹

Providing Adequate Hand Washing Facilities

Restaurants in all 45 localities surveyed are required to have a hand washing sink and hot water. However,

employees need to be trained about the importance of washing their hands to prevent the transmission of some pathogens.

Critical Violations of Food Safety Regulations

The FDA Food Code recommends that a restaurant be required to correct the most critical violations of food safety standards at the time the inspector discovers them.⁷² Critical violations are defined as those more likely than others to cause food contamination and/or illness. All but two of the agencies surveyed complied with this requirement. Kansas City, Missouri, and Pitkin County, Colorado, do not require immediate correction of these violations. Instead, they give restaurants a minimum of 48 hours to remedy critical violations.

The Food Code also recommends that restaurants be given no more than 10 days to remedy critical violations. Some agencies allow much more time for restaurants to make these corrections. The state of Vermont and Mecklenburg County, North Carolina, give restaurants almost a month to comply.

Some respondents mentioned the political difficulties of closing restaurants that violate local health laws. In some

jurisdictions, health department officials do not have the authority to shut down a restaurant and must present their case to officials in other departments who have the authority to do so. In jurisdictions where officials with the authority to close restaurants are politically appointed, the recommendation to take away a business permit and close a restaurant can become extremely sensitive.

One Midwestern health department official told CSPI of a situation where the health official wanted to issue citations to restaurants for various code violations but did not have the authority to do so. In this locality, the authority to close a restaurant rested with the community development department, whose politically appointed director refused to deliver the citations on the grounds that he "did not have time" to do it. A health department official in Florida told CSPI that the state was not really aggressive in closing restaurants and often made two follow-up visits to violators and sometimes even a third.

The Limits of Local Government Enforcement

Local health departments are hampered by tight budgets. Many of the respondents mentioned the frustration of trying to do a good job in the midst of budget and staff cutbacks. A food inspector in Kentucky summed up the major issues facing restaurant inspectors today as (1) cuts in health department budgets; (2) the increasing variety of food being served by fast-food restaurants, which makes restaurant inspections more difficult and time-consuming, and (3) extremely high turnover of food service personnel, which makes training of workers a continuous, time-consuming and expensive process. For example, in Jefferson County, Kentucky, the food inspector reported a 250% turnover of food-service personnel each year.

Local health departments are also constrained by the codes that have been adopted in their county or state. Several respondents mentioned that their agencies recommend that restaurants follow the latest

FDA Food Code standards, but the agencies are only able to enforce the standard that is on the books in their jurisdiction.

Even where local health departments have adequate funding and have adopted the latest FDA Food Code, they cannot guarantee that restaurants are preparing food safely at all times. An inspection every six months does not ensure restaurant compliance during the rest of the year. The ultimate responsibility for food safety lies with each restaurant to make sure that its employees are following the highest food safety standards. Food service workers need to be educated about the risks inherent in food handling, such as foods that are likely to harbor bacteria and handling practices that may lead to cross-contamination. Even though training employees is ultimately the responsibility of restaurants, at least nine of the localities surveyed require all food service workers to receive food safety training.

WHAT RESTAURANTS CAN DO TO IMPROVE FOOD SAFETY

While regular inspections and enforcement of uniform standards by state and local agencies are important to assure food safety, many restaurants are already improving the safety of their meals. Every restaurant, whether it is a fast-food chain or a four-star gourmet establishment, can take steps to ensure the safety of the food it prepares and serves its customers. Restaurants can design programs to reduce the risks in their particular operations using the principles of Hazard Analysis and Critical Control Points (HACCP). HACCP (pronounced "hass-up") principles are used in many segments of the food industry, and have recently been mandated for slaughterhouses, seafood processors, and many food processing plants.⁷³

Using HACCP, restaurant managers identify critical points where food safety risks can occur and develop measures to control those risks. For example, in preparing roast beef, critical control points might include handling of the raw meat; cooling of the cooked meat; reheating the meat; deboning or slicing the meat; and holding the meat in a warming cabinet just before serving.⁷⁴ If a restaurant identifies those potentially risky steps, it can also devise steps to ensure that the meat is not contaminated (or does not contaminate other food) at each step.

To assist restaurants of any size in developing HACCP plans, the Chicago-based Educational Foundation of the National Restaurant Association offers a HACCP training program called ServSafe. Offered for sale as part of the program are a coursebook based on 1993 FDA Food Code standards that certifies restaurant managers

in HACCP principles; workbooks, posters, videos, and slides for training staff; and a reference book containing 1993 Food Code time and temperature standards.⁷⁵ The ServSafe program has certified 600,000 restaurant managers since it began in 1987, the majority of them from national chains. State affiliates of the Educational Foundation of the National Restaurant Association offer ServSafe training and materials to small establishments, often at a discount.

Another source of HACCP information is the 1995 FDA Food Code. The Food Code contains an appendix that describes HACCP principles and provides guidance on identifying hazards and critical control points in restaurant operations.

Restaurants should realize that preventing food poisoning is not only good for the health of customers, but for restaurants' economic health as well. A publicized food poisoning outbreak can drastically affect a restaurant's reputation among consumers and can even shut a restaurant down altogether.

A pilot program being planned in Washington, D.C. called "Extra Step" will help restaurants use their food safety programs as a marketing tool.⁷⁶ "Extra Step" is a joint effort between restaurants, their trade association, and the Washington, D.C. restaurant inspection agency. In order to be granted "Extra Step" status, restaurants must have an approved HACCP plan, conduct training for all food preparation staff twice a year, and receive 90% sanitation ratings for three regularly scheduled quarterly inspections. Restaurants

will be able to use the “Extra Step” symbol in advertising, on menus, and on signs in the restaurant.

To learn what restaurants are doing to improve food safety, CSPI talked to four

restaurant companies about their programs: two fast-food chains, a table-service seafood chain, and a family-owned restaurant.⁷⁷

Jack in the Box: A Farm-to-Table HACCP System

Following the deadly *E. coli* O157:H7 outbreak in the Northwestern U.S. in 1992 and 1993 that was traced to contaminated hamburger served at Jack in the Box restaurants, Foodmaker, the chain’s parent company, implemented one of the most comprehensive HACCP programs in the restaurant industry.⁷⁸ The HACCP program and food safety are fully integrated into all aspects of the company’s operation and are part of each restaurant’s management system. The Foodmaker company, with revenues of \$1 billion each year, is based in San Diego, California, and has more than 1,250 stores, primarily in 12 Western and Southwestern states.⁷⁹

Step One: The Suppliers

Foodmaker maintains tight control over the hamburger patties it buys through strict specifications it has established for its patty suppliers. For example, suppliers must consistently monitor and verify meat temperature, completely wash processing equipment at least once per shift, and document the sources of their product. The patty suppliers must verify where the slaughterhouses bought the meat, when it was processed, and under what conditions.⁸⁰

Step Two: Microbial Testing

Foodmaker requires its suppliers to test for microbial pathogens on every tractor-trailer load of meat and to document the results. Any product found to be contaminated with *E. coli* O157:H7 is

destroyed, according to company policy.⁸¹ If a supplier’s meat products test positive for *E. coli* O157:H7 more than once, Foodmaker stops buying from it. In addition, Foodmaker conducts its own microbial tests on composite samples of meat taken from each tractor-trailer load of meat.

Step Three: Temperature Controls During Shipping

Foodmaker’s patties are shipped frozen. The company requires its suppliers to seal the doors of delivery trucks and record the temperature inside with temperature monitors. All shipments contain a sealed “black box” temperature recorder that charts the trailer temperature during transit. When the meat is delivered to the warehouse, inspectors check to see if the doors were ever opened, exposing the meat to warmer air. When delivering to restaurants, drivers are required to unload the hamburger patties from truck to restaurant freezer within twenty minutes.

Step Four: Avoiding Cross-Contamination in the Kitchen

To reduce the risk of cross-contamination, Jack in the Box cooks hamburger patties from a frozen state. Frozen meat patties do not leak juices that can contaminate other foods and are easier to handle with utensils. Jack in the Box also forbids its employees to directly touch raw

meat with their hands. Instead, all hamburger patties are handled with utensils.

Step Five: Insuring Adequate Cooking Temperatures

Cooks are required to cook hamburger patties until they reach internal temperatures of greater than 155°F, the

temperature at which *E. coli* O157:H7 bacteria are killed. The temperature is verified with a probe thermometer designed to give instantaneous heat readings of different parts of each patty.⁸² A Jack in the Box restaurant will not serve a rare or medium rare hamburger to a customer, even upon request.

Taco Bell: Using Technology for Food Safety

Taco Bell, with 4,600 restaurants nationwide, is the world's largest Mexican fast-food restaurant.⁸³ Over 55 million U.S. customers eat at Taco Bell each week. Taco Bell's corporate headquarters are in Irvine, California.

Step One: Food Preparation

To eliminate the risk that food will be cooked at insufficient temperatures, Taco Bell has removed the cooking of food from its restaurants.⁸⁴ All food is cooked and hermetically sealed in plastic bags in central manufacturing centers under a rigorous HACCP plan, which includes microbial testing for *E. coli* O157:H7 and other pathogens. Depending on the type of food, it is then shipped frozen or refrigerated at 40°F to the restaurants, where managers monitor its temperature. The food, still in plastic bags, is reheated in boiling water until it reaches 165°F.

Step Two: Temperature Control

Taco Bell has introduced a system in some of its restaurants designed to alert staff to temperature violations. The reheated food, such as ground beef or beans, is held on a heating table until it is assembled into food products sold by the restaurant. The heating table and the cooling equipment that holds fresh produce are connected to a monitor, which turns on an audible alarm

system in the restaurant if temperatures fall outside the safety range. If the problem is not corrected within a specified amount of time, a second alarm is issued. A telephone call is automatically made to corporate headquarters in Irvine, California, where a staff person will call the restaurant back to find out why the problem has not been remedied.

Step Three: Training and Safety Audits

Every manager of a Taco Bell restaurant is required to be certified under the ServSafe program. Taco Bell has a food safety audit system in which random audits of critical control points are conducted of each restaurant. The auditor checks temperatures and employee hand washing records. Employees are required to wash their hands every 60 minutes and after completing tasks that require hand washing, and to make a written record each time they do so.

Despite this system, health officials linked a 1995 hepatitis A outbreak in Salt Lake City, Utah, to a Taco Bell employee, which shows that even a well-designed HACCP system can fail. A company vice-president stated that records showed no irregularities in employee hand washing around the time of the outbreak and denied that Taco Bell was responsible for the outbreak.⁸⁵

Legal Sea Foods: Controlling the Risks of Fish and Shellfish

Legal Sea Foods has been in business for about 40 years and now has 13 restaurants throughout the Northeast.⁸⁶ Fish processing for all Legal Sea Foods restaurants is done in the same plant located in Allston, Massachusetts, under a U.S. Department of Commerce-certified HACCP program.

Step One: Buying from Reputable Suppliers

Legal Sea Foods has one buyer who buys all the seafood for its restaurants.⁸⁷ He selects all seafood directly from the docks, choosing only the freshest fish: fish caught on the last day the boat was at sea. Legal Sea Foods has 40-year relationships with some of its suppliers.

Step Two: Shipping the Seafood

Three to four times a week, processed fish is shipped from the Allston plant to the restaurants. The fish is shipped by truck in insulated, temperature-controlled containers. Computerized trip monitors record temperatures inside the containers from the time they leave the Allston plant to the time they arrive at the restaurants. The company maintains records of the computer print-outs from every trip.

Step Three: Monitoring and Recording Seafood Quality

Each Legal Sea Foods restaurant has procedures in place for recording the condition of seafood as it arrives. Restaurant workers examine the raw seafood

for color and odor. They also set shelf life dates for each species of seafood according to an industry book of shelf life values. Daily inspections are conducted, and seafood that has exceeded its allowable shelf life is discarded immediately.

Step Four: Laboratory Testing

Once a month, the company's head sanitarian visits each Legal Sea Foods restaurant to conduct a complete inspection. During the sanitarian's inspection, bacterial swabs are taken of a water glass, a fork, a coffee cup, three cutting boards, and three different pieces of raw fish, usually shrimp, squid and scallop. Also swabbed are ice cream and coleslaw, both made on the restaurant's premises. The samples are tested at Legal Sea Foods' laboratory to determine whether they contain coliform bacteria, a sign that pathogens may be present. A report of the laboratory's findings is prepared.

Step Five: Internal Quality Assurance Checks

While at the restaurant, the sanitarian does a complete quality assurance audit, checking the restaurant's storage facilities, adherence to product shelf life schedules, whether food handlers are wearing sanitary gloves, and whether the restaurant is properly recording hot holding temperatures. Because the score of two consecutive audits affects the restaurant manager's salary, audits are taken very seriously by restaurant staff.

That's Amore: Food Safety in a Small Restaurant

That's Amore, located in Hale's Corners, Wisconsin, serves Italian and American food to about 2,500 customers a week. Owner Joe Lopiparo has operated the small restaurant for seven years and has implemented a program that focuses on thorough training of his staff.⁸⁸

Step One: The Best Defense -- An Educated Staff

All kitchen staff at That's Amore is required to be certified under the ServSafe program. Mr. Lopiparo, who is certified himself, pays \$125 per employee for training offered through the Education Foundation of the Wisconsin Restaurant Association. This is made easier by the low turnover rate of That's Amore's staff: the newest cook has been there for over two years.

Kitchen staff meetings are held weekly so that employees can discuss food handling practices. The kitchen manager meets monthly to discuss food safety with the wait staff, although they are not involved in food preparation.

Step Two: Buying and Storing Safe Food

That's Amore relies on one large well-established supplier for most of its food. The restaurant receives frequent deliveries to assure that food is fresh, buying produce daily and steak three times a week. All incoming food is checked in by the kitchen manager, who measures the temperature of food that requires refrigeration. All dry and canned goods are marked with the date they arrived.

All prepared foods are also marked with the date they were prepared and the

name of the employee who prepared them. The staff is trained to use a risk-averse approach, following the rule, "When in doubt, throw it out."

Step Three: Cooking and Cooling Temperatures

Every dish served at That's Amore is made according to a detailed recipe that includes specific temperatures at the cooling and heating steps. All staff members are instructed that microbes can multiply rapidly between 50°F and 140°F. The cooks use thermometers to make sure sauces and meats are hot enough or cool enough during each stage of food preparation. When cooling a large batch of spaghetti sauce, employees transfer the sauce into several pans less than four inches in depth, stir the sauce, and refrigerate it.

That's Amore does not serve raw foods. The restaurant does serve hamburgers, although they account for less than 2% of the meals served.⁸⁹ The cooks generally do not measure the internal temperature of hamburgers with a thermometer, but they cook the hamburgers until they are no longer pink inside. However, if a customer requests a medium-rare burger, he or she will be served one.

Step Four: Avoiding Cross-Contamination

That's Amore has separate, color-coded cutting boards for beef, poultry, and seafood. At a cook's suggestion, the knives are color-coded as well. Water with bleach is readily available at all work stations in the kitchen for wiping down surfaces. When preparing raw food, employees wear gloves.

CONCLUSIONS AND RECOMMENDATIONS FOR ACTION

Illnesses caused by restaurant food sicken millions and kill thousands of Americans each year. Yet, as CSPI's survey documents, most state and local health departments are not requiring restaurants to prepare and serve the safest food possible. Even though a federal standard for food safety exists, the vast majority of the jurisdictions surveyed have outdated standards. Where state and local legislatures have not adopted the most recent version of the Food Code, health departments are unable to enforce it.

The health departments that CSPI surveyed are also hampered in their efforts by insufficient budgets. At a time when recent federal laws increasingly shift burdens that have traditionally been federal responsibilities to states, health department budgets are likely to prove even more inadequate to protect restaurant customers.

Even in jurisdictions that have adopted the latest FDA Food Code and have adequately funded their health departments, the ultimate responsibility for food safety lies with restaurants. Since most foodborne illness is easily preventable, restaurants can and should take steps to improve food safety in their establishments and to decrease the rate of illness. Jack in the Box, Taco Bell, Legal Sea Foods, and That's Amore provide examples of how restaurants can take the initiative to improve the safety of the food they serve. Other restaurants, with the assistance of state and local governments and trade associations, should develop similar programs tailored to their operations.

Restaurants, local and state governments, and the federal government should take these key steps to increase the

safety of food served in the nation's restaurants:

- All state and local governments should incorporate the 1995 FDA Food Code's food safety standards into their laws governing inspection, and should update their laws whenever the Food Code is updated.
- State and local governments should mandate that restaurants utilize HACCP systems to improve the safety of the meals they serve. Local health authorities should assist restaurants in setting up and monitoring HACCP plans, and should verify that HACCP plans are working by conducting periodic laboratory testing of food and equipment samples taken from restaurants. Inspectors should have the proper equipment to measure cooking temperatures of food during inspections.
- State and local governments should make restaurant food safety a higher budgetary priority and should ensure that local inspection agencies have sufficient funds to carry out their functions.
- State and local governments should work with restaurants and restaurant trade associations to develop food safety recognition programs for restaurants. Eligible restaurants should be those that have consistently maintained safe operations and that have instituted HACCP systems, including comprehensive, ongoing training programs for their employees. Such

restaurants could be recognized by the awarding of a “seal of approval” that could be displayed as a window decal and used in advertising.

- FDA should revise the Food Code to include model inspection forms that focus on the most critical violations that affect food safety, rather than on more technical violations. The model forms, used by many jurisdictions, should be designed to help inspectors effectively target violations that jeopardize public health during their limited time in each restaurant.
- The FDA Food Code should include generic HACCP models for different types of restaurants, with guidance to local health agencies for assisting restaurants in setting up the plans.
- Even if not required to do so by law, all restaurants should establish HACCP plans to identify and control the risks of foodborne illness in their operations.
- Since harmful pathogens frequently contaminate the food supply, particularly seafood, meat, poultry, and eggs, HACCP plans should contain provisions for restaurants to monitor the quality of products they receive from suppliers, including the use of temperature monitoring devices during shipping and laboratory testing of suppliers’ products. Restaurant HACCP plans

should require that suppliers implement their own HACCP plans to ensure the safety of food from the farm through the processing and shipping stages.

- Food-service workers and their supervisors should be required to undergo training in food safety, as at least nine jurisdictions already require. State and local health agencies should mandate that restaurants provide such training, or alternatively should offer courses for workers funded by restaurants.
- To encourage the adoption of uniform standards, Congress should allocate money for increased restaurant inspection and enforcement to states that adopt the FDA Food Code’s food safety and inspection standards. The money should not be taken from the existing budgets of federal food safety agencies.
- On both the state and federal levels, additional funding should be allocated for epidemiological studies of foodborne illness.
- The U.S. Department of Agriculture (USDA) and FDA should step up their efforts to ensure that seafood, meat, poultry, and eggs are as free from harmful bacteria and other contaminants as possible.

Table II. Health Department Survey Results¹

Jurisdiction	Number of Inspections in 1994 Per Restaurant (Reported)	Number of Inspections in 1994 per Restaurant (Calculated by CSPI from data)	Average Time per Inspection	Time Allowed to Correct Critical Violations	Samples Taken During Routine Inspection for Laboratory Testing?	Warnings on the danger of eating raw foods required?
1995 FDA Food Code	2 (Every six months)	Not applicable	No requirement	At time of inspection (ATOI) to 10 days	No requirement	Yes
Northeast						
City of Hartford, CT	3 to 4 based on risk	No data given	20 min.	ATOI to 10 days	No	No
City of Portland, ME ²	1	1.03	1 hr.	ATOI to 10 days	No	No
City of Boston, MA	2	No data given	No data given	ATOI to 10 days	No	No
City of Concord, NH	2.5	No data given	1 hr. 6 min	ATOI to 24 hours	No	No
Erie County, NY (Buffalo)	0.5 to 2 based on risk	1.7	1 hr. 30 min.	ATOI	No	No
City of New York, NY	1	No data given	1 hr. 30 min.	ATOI to 14 days	Yes	No
State of Rhode Island	0.67	No data given	2 hr. 30 min	ATOI	No	Yes
State of Vermont	1.25	1.58	54 min	ATOI to 4 weeks	No	No
Mid-Atlantic						
State of Delaware	1	1.49	1 hr.	ATOI to 48 hours	No	No
City of Baltimore, MD	1	0.9	3 hrs.	ATOI	No	No
Atlantic County, NJ (Excludes Atlantic City)	1	0.87	1 hr. 30 min.	ATOI to 24 hours	No	No
City of Cleveland, OH	1	1.1	1 hr. 12 min	ATOI	No	No
Allegheny County, PA (Pittsburgh)	2 (Number varies based on risk)	No data given	1 hr. 18 min.	ATOI to 48 hours	No	No
City of Philadelphia, PA	0.75	No data given	1 hr. 37 min	ATOI to 48 hours	Data not tabulated	No
Washington, DC	4	1.9	1 hr	ATOI to 10 days	Yes	No

¹ Entries in **bold** do not comply with FDA Food Code.

² Since this report was released, the health department in Portland, Maine, has notified CSPI by telephone that some of the information reported to CSPI by the department does not accurately reflect the department's standards. CSPI has requested, but has not yet received from the department, written confirmation of these standards.

Jurisdiction	Cooking Temperature Standards (°F)					Reheating Standard (°F)	Cooling Standard (°F)	Refrigeration Standard (°F)	Hot Holding Standard (°F)	% of Standards Adopted
	Poultry	Eggs	Whole Fish	Pork	Ham-burger					
1995 FDA Food Code	165	145	145	155	155	165	140 to 70 w/i 2 hrs.; 70 to 41 w/i 4 hrs.	41	140	100%
Northeast										
City of Hartford, CT	165	165	165	165	None	165	To 45 w/i 4 hrs.	45	140	67%
City of Portland, ME	None	None	None	None	None	165	None	40	140	33%
City of Boston, MA	165	140	140	150	140	165	To 45 w/i 4 hrs.	45	140	42%
City of Concord, NH	165	145	145	155	155	165	140 to 70 w/i 2 hrs.; 70 to 41 w/i 4 hrs.	41	140	92%
Erie County, NY (Buffalo)	165	145	140	150	140	165	120 to 70 w/i 2 hrs.; 70 to 45 w/i 4 hrs.	45	140	42%
City of New York, NY	165	145	140	150	155	165	140 to 70 w/i 2 hrs.; 70 to 45 w/i 4 hrs.	45	140	42%
State of Rhode Island	165	145	145	155	155	165	140 to 70 w/i 2 hrs.; 70 to 40 w/i 4 hrs.	41	140	92%
State of Vermont	165	None	140	150	155	165	To 40 w/i 4 hrs.	40	140	50%
Mid-Atlantic										
State of Delaware ³	165	140	None	150	155 ⁴	160 ⁵	To 45 w/i 4 hrs.	45	140	25%
City of Baltimore, MD	165	140 ⁶	140	155	155 ⁶	165	140 to 70 w/i 2 hrs; 70 to 41 w/i 4 hrs.	45	165	58%
Atlantic County, NJ (Excludes Atlantic City)	165	140	140	150	None	165	120 to 70 w/i 2 hrs.; to 45 w/i 4 hrs.	45	140	33%
City of Cleveland, OH	165	165	None	165	155	165	To 45 w/i 4 hrs.	45	140	58%
Allegheny County, PA (Pittsburgh)	165	140	140	140	155	165	To 70 w/i 2 hrs.; 70 to 45 w/i 4 hrs.	45	140	50%
City of Philadelphia, PA	165	145	145	155	155	165	140 to 45 w/i 2 hrs. ⁷	45	140	67%
Washington, DC	165	145	145	155	155	160	140 to 70 w/i 2 hrs.; 70 to 41 w/i 4 hrs.	45	140	75%

³ Since this report was released, the health department in the State of Delaware has notified CSPI by telephone that some of the information originally reported to CSPI by the department (marked with an asterisk) does not accurately reflect the department's standard. CSPI has requested, but has not yet received from the department, written confirmation of this standard.

⁴ The State of Delaware requires that the internal temperature of hamburger patties reach 140°F for 8 minutes, 145°F for 2 minutes, 150°F for 30 seconds, or 155°F for 7.8 seconds. The FDA temperature and time specification for cooking hamburger is 145°F for 3 minutes, 150°F for 1 minute, or 155°F for 15 seconds. (FDA Food Code, 1995. §§ 3-401.11(2); 3-401)

⁵ Unless customer requests otherwise.

⁶ The temperature of fast-food hamburgers is not measured during inspections in this jurisdiction

⁷ These temperatures were in effect at the time the survey was conducted, in January through February of 1996. The City of Philadelphia Department of Health has notified CSPI that new regulations taking effect around November 1996 will change Philadelphia's cooling and refrigeration standards to a low of 41°F in compliance with the 1995 FDA Food Code.

Jurisdiction	Number of Inspections in 1994 Per Restaurant (Reported)	Number of Inspections in 1994 per Restaurant (Calculated by CSPI from data)	Average Time per Inspection	Time Allowed to Correct Critical Violations	Samples Taken During Routine Inspection for Laboratory Testing?	Warnings on the danger of eating raw foods required?
1995 FDA Food Code	2 (Every six months)	Not applicable	No requirement	At time of inspection (ATOI) to 10 days	No requirement	Yes
Southeast						
Jefferson County, AL (Birmingham)	1 to 5 based on risk	3.49	1 hr.	ATOI	No	No
Hillsborough County, FL (Tampa)	3	2.97	1 hr. 45 min.	ATOI to 24 hours	No	Yes ^a
Fulton County, GA (Atlanta)	2	0.97	1 hr.	ATOI to 10 days	No	No
Jefferson County, KY (Louisville)	1.7	1.98	1 hr. 45 min.	ATOI to 5 days	No	No
Mecklenburg County, NC (Charlotte)	4	3.61	1 hr. 21 min.	ATOI to 30 days	No	No
Charleston County, SC (Charleston)	4	3.5	45 min.	ATOI to 72 hours	No	No
Davidson County, TN (Nashville)	2	2.54	45 min.	ATOI to 10 days	No	No
Monongalia County, WV	2	No data given	1 hr.	ATOI to 10 days	No	No
Midwest						
City of Chicago, IL	2	1.98	1 hr. 30 min.	ATOI to 48 hours	Yes	Yes
Marion County, IN (Indianapolis)	2	1.71	1 hr. 15 min.	ATOI to 7 days	No	No
City of Detroit, MI	1.5	1.5	2 hrs.	ATOI to 5 days	No	No
Burleigh County, ND (Bismarck)	3.75	3	1 hr. 30 min.	ATOI to 10 days	No	No
Southwest						
Pulaski County, AR (Part of Little Rock)	2	No data given	50 min.	ATOI to 1 week	Yes	No
Pitkin County, CO (Aspen)	2	2.14	1 hr. 7 min.	48 hours	No	No
Linn County, IA (Cedar Rapids)	1	1.3	2 hrs.	ATOI to 48 hours	No	No
Jackson County, MO (Excludes Kansas City)	1	1.4	1 hr.	ATOI to 10 days	No	No
Kansas City, MO	2	1.67	45 min.	48 hours to 10 days	No	No
Douglas County, NE (Omaha)	2	1.92	1 hr.	ATOI to 48 hours	No	No
Bernalillo County, NM (Albuquerque)	4	3.75	1 hr. 30 min.	ATOI to 24 hours	No	Yes
Tulsa County, OK (Tulsa)	2 to 4 based on risk	3.68	1 hr.	ATOI	No	No
City of Dallas, TX	2	4.02	53 min.	ATOI	No	No
Salt Lake County, UT (Salt Lake City)	2	1.81	50 min.	ATOI to 48 hours	Data not tabulated	No

^a For oysters only

Jurisdiction	Cooking Temperature Standards (°F)					Reheating Standard (°F)	Cooling Standard (°F)	Refrigeration Standard (°F)	Hot Holding Standard (°F)	% of Standards Adopted
	Poultry	Eggs	Whole Fish	Pork	Ham-burger					
1995 FDA Food Code	165	145	145	155	155	165	140 to 70 w/i 2 hrs : 70 to 41 w/i 4 hrs	41	140	100%
Southeast										
Jefferson County, AL (Birmingham)	165	140	140	150	155	165	To 45 w/i 4 hrs.	45	140	42%
Hillsborough County, FL (Tampa)	155	140	140	150	155	165	140 to 45 w/i 4 hrs.	45	140	50%
Fulton County, GA (Atlanta)	165	None	None	150	None	165	140 to 45 w/i 4 hrs.	45	140	42%
Jefferson County, KY (Louisville)	165	140	140	150	140	165	None	45	140	33%
Mecklenburg County, NC (Charlotte)	165	140	None	150	155 ⁹	165	None	45	140	42%
Charleston County, SC (Charleston)	165	None	None	155	155	165	130 and put in cooler	45	130	50%
Davidson County, TN (Nashville)	165	140	None	155	140	165	140 to 45 w/i 4 hrs.	45	140	50%
Monongalia County, WV	165	140	140	140	155	165	To 45 w/i 4 hrs.	45	140	50%
Midwest										
City of Chicago, IL	145	145	145	145	155	165	140 to 70 w/i 2 hrs.; 70 to 40 w/i 4 hrs.	40	140	83%
Marion County, IN (Indianapolis)	165	140	140	150	155	165	To 45 w/i 4 hrs.	45	140	50%
City of Detroit, MI	165	None	140	150	140	165	To 45 w/i 4 hrs.	45	140	33%
Burleigh County, ND (Bismarck)	165	140	None	150	155	165	140 to 45 w/i 4 hrs.	45	140	50%
Southwest										
Pulaski County, AR (Part of Little Rock)	165	140	None	140	155	165	140 to 40 w/i 4 hrs	45	140	58%
Pitkin County, CO (Aspen)	165	None	None	150	155	165	To 45 w/i 4 hrs.	45	140	42%
Linn County, IA (Cedar Rapids)	165	None	None	130	155	165	To 45 w/i 4 hrs.	45	140	42%
Jackson County, MO (Excludes Kansas City)	165	None	None	150	None	165	To 45 w/i 4 hrs.	45	140	33%
Kansas City, MO	165	None	None	150	155	165	To 45 w/i 4 hrs.	45	140	42%
Douglas County, NE (Omaha)	165	145	145	150	155	165	145 to 45 w/i 4 hrs.	45	140	67%
Bernalillo County, NM (Albuquerque)	165	120	160	170	155	185	To 72 w/i 2 hrs.; to 40 w/i 4 hrs.	42	155	83%
Tulsa County, OK (Tulsa)	165	None	None	150	155	165	To 45 w/i 4 hrs.	45	140	50%
City of Dallas, TX	150	140	140	140	140	165	To 45 w/i 4 hrs.	45	140	33%
Salt Lake County, UT ¹⁰ (Salt Lake City)	165	None	None	165	155	165	To 45 w/i 4 hrs.	45	140	58%

⁹ The temperature of fast-food hamburgers is not measured during inspections in this jurisdiction

¹⁰ Salt Lake County did not have cooking temperature requirements for eggs and whole fish at the time the survey was conducted, in January through February of 1996. The Salt Lake County Department of Health has notified CSPI that new regulations that took effect on October 15, 1996 brought Salt Lake County's inspection requirements into compliance with the 1995 FDA Food Code.

Jurisdiction	Number of Inspections in 1994 Per Restaurant (Reported)	Number of Inspections in 1994 per Restaurant (Calculated by CSPI from data)	Average Time per Inspection	Time Allowed to Correct Critical Violations	Samples Taken During Routine Inspection for Laboratory Testing?	Warnings on the danger of eating raw foods required?
1995 FDA Food Code	2 (Every six months)	Not applicable	No requirement	At time of inspection (ATOI) to 10 days	No requirement	Yes
West						
Maricopa County, AZ (Phoenix)	3	2.83	1 hr. 21 min.	ATOI to 48 hours	No	No
Los Angeles County, CA (Los Angeles)	2.5	2	40 min.	ATOI to 24 hours	No	Yes
City and County of San Francisco, CA	3	2.48	40 min.	ATOI to 5 days	No	Yes
State of Hawaii	2	1.21	1 hr.	ATOI to 48 hours	No	No
Central District, ID (Boise)	1	1.53	1 hr. 30 min.	ATOI	Yes	No
Clark County, NV (Las Vegas)	2 to 4 based on risk	2.27	35 min.	ATOI	No	No
Lane County, OR (Eugene)	2	No data given	1 hr.	ATOI	No	No
King County, WA (Seattle)	2.68	2.27	1 hr. 18 min.	ATOI	No	Yes
Percent of All Jurisdictions Following FDA Standard	67%	Not applicable	Not applicable	89%	Not applicable	16%

Jurisdiction	Cooking Temperature Standards (°F)					Reheating Standard (°F)	Cooling Standard (°F)	Refrigeration Standard (°F)	Hot Holding Standard (°F)	% of Standards Adopted
	Poultry	Eggs	Whole Fish	Pork	Ham-burger					
1995 FDA Food Code	165	145	145	155	155	165	140 to 70 w/i 2 hrs : 70 to 41 w/i 4 hrs	41	140	100%
West										
Maricopa County, AZ (Phoenix)	165	None	140	165	140	165	To 70 w/i 2 hrs.; 70 to 45 w/i 4 hrs.	45	140	50%
Los Angeles County, CA (Los Angeles)	None	None	None	None	None	140	140 to 70 w/i 2 hrs.; 70 to 41 w/i 4 hrs.	45	140	42%
City and County of San Francisco, CA ¹¹	None*	None	None*	None*	None*	140	To 45 as quickly as possible	45	140	33%
State of Hawaii	165	None	None	150	155 ¹²	165	To 45 w/i 4 hrs.	45	140	50%
Central District, ID (Boise)	165	145	145	155	155	165	To 45 w/i 4 hrs.	45	140	67%
Clark County, NV (Las Vegas)	165	165	165	165	145	None	None	45	145	58%
Lane County, OR (Eugene)	165	None	None	None	155	165	To 45 w/i 4 hrs.	45	140	50%
King County, WA (Seattle)	165	140	140	150	155 ¹³	165	140 to 45 w/i 4 hrs.	45	140	58%
										Average: 51%
Percent of All Jurisdictions Following FDA Standard	86%	27%	22%	31%	64%	89%	20%	11%	98%	Not applicable

¹¹ Since this report was released, the health department in San Francisco has notified CSPI by telephone that some of the information originally reported to CSPI by the department (marked with asterisks) does not accurately reflect the department's standards. CSPI has requested, but has not yet received from the department, written confirmation of these standards.

¹² Unless customer requests otherwise.

¹³ Five temperatures are taken on each of three patties. All temperatures must be 155°F or above; otherwise, the median temperature should not be less than 160°F and no temperature should be below 145°F.

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THE VICTIMS THAT GOT AWAY: INEFFECTIVE FEDERAL SURVEILLANCE OF SEAFOOD-BORNE ILLNESS

The exact number of seafood victims nationwide continues to remain a mystery as a result of the inadequacy of the federal disease surveillance system. At least half of the individual victims documented in this report, for example, were never reported as having seafood illnesses to the Centers for Disease Control.

Underreporting of seafood-borne illness is widespread throughout the country's state public health agencies. Since federal public health agencies, such as CDC and FDA, base their assessments of the extent of seafood-borne illness on officially reported cases from state or local health departments, such reporting failures inevitably lead to massive underestimates of the actual incidence of seafood illnesses. This serious deficiency in public health surveillance and risk assessment was confirmed by Public Voice's recent survey of 49 state health departments and the District of Columbia.

Specifically, Public Voice found the following barriers to the reporting of seafood-borne illnesses:

- ▶ The food source causing a food-borne illness usually is not defined. Health officials in 66 percent of the states said that the food responsible for an illness could not be detected at least half the time.
- ▶ Most illnesses that are primarily seafood-borne are not required to be reported. Only two states have ciguatera on their list of reportable illnesses; two listed scombroid poisoning; 14 list vibrio-related illnesses; and none list Norwalk viruses. None of these illnesses are on the Center for Disease Control's list of nationally notifiable diseases.

- ▶ Doctors often don't diagnose or report seafood-borne illness to state health departments. Nearly 70 percent of state health departments said that doctors do not realize that seafood-borne illnesses should be reported. Eighty-three percent said that doctors do not diagnose seafood-borne illnesses.
- ▶ Forty-two percent of state health departments identified lack of enforcement of reporting requirements and 51 percent identified underfunding of their departments as barriers to complete reporting of food-borne illnesses.

The absence of a comprehensive, reliable surveillance system for seafood-borne illness leaves consumers at greater risk of being victimized by contaminated seafood. Without complete information about the actual incidence of seafood-borne illnesses, federal regulators are unable to accurately assess the risk to consumers and they cannot effectively target their consumer protection activities. Moreover, the federal government's failure to account for the victims of seafood-borne illnesses invariably leaves the public in the dark about the extent of the problem and prevents federal regulators from being held fully accountable for the inadequacies of their public health programs.





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INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

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Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although food outbreaks are sometimes local because of improper processing or handling, most outbreaks implicate federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products. In some instances, on-site assistance is requested by the local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem. For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

Companies responsible for affected products also have a critical role to play. Food companies are sometimes the first to recognize that their product is causing illness. In addition, food product recalls are voluntary, although FDA may request a company to recall products. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort.

The early warning capability of FoodNet and the strengthening of state surveillance capacity and federal-state communications will enhance appropriate involvement of federal agencies in the investigation of foodborne disease outbreaks. ~~An essential factor in effective response to foodborne outbreaks is rapid communication and exchange of information among the appropriate federal, state, and local government agencies.~~

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recommendations

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. When this occurs, it is essential that federal agencies speak with one voice. *As part of this initiative*

Insert
The agencies have streamlined their outbreak response procedures.
The lead department in any foodborne illness outbreak will be determined by regulatory jurisdiction over the food products implicated in the outbreak. FSIS has regulatory responsibility for meat, poultry, and egg products, so USDA will be the lead when these products are involved. Since FDA has regulatory responsibility for all other foods, HHS will be the lead when any other food product is involved. Where there is overlap, both HHS and USDA will have leadership responsibility. EPA will continue to be the lead agency for outbreaks traced to drinking water. Each agency will designate a Coordinator.

This new management system will provide a common set of objectives and strategies and one spokesperson that will speak on behalf of the federal government. Once there are indications to federal or state agencies of a large-scale problem, the staff will tell the Coordinator who will then coordinate the response among federal and state agencies. ~~Notification to the appropriate~~

~~Cabinet-level official and ongoing communication with Cabinet Affairs in the White House will be part of the continuing role of the Coordinator.~~

FSIS has established an Emergency Response Program to prevent and control foodborne disease outbreaks involving meat, poultry, and egg products. Likewise, FDA's Division of Emergency and Investigational Operations serves this function for all other food products. Both FDA and FSIS maintain 24-hour telephone service staffed with a duty officer trained to respond to emergencies and ongoing illnesses, including foodborne illness and outbreaks, who have access to emergency personnel throughout the agency, as well as with emergency contacts in other agencies. FDA's Division of Emergency and Investigational Operations will serve to coordinate with other agencies. CDC provides 24-hour emergency consultation for botulism and other foodborne disease clinical emergencies and stations Epidemic Intelligence Service officers in 15-20 states each year to support surveillance and emergency response at the state level.

A critical element of an effective, rapid response to a foodborne illness outbreak is ready communication, by all the involved parties at the federal, state, and local level. Although there are communication systems in place, they need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak response personnel in each agency at the federal, state, and local levels. This strengthened system will complement the data and information exchange systems described in the "Early Warning for Foodborne Disease Surveillance" section of this report.

~~Rapid communication of data and information about foodborne illness outbreaks is an essential factor in preventing and controlling outbreaks.~~ In order to improve communications with state agencies, FDA has adopted a fax-on-demand and fax broadcast system. The fax broadcast system, containing a database of more than 900 state officials, permits messages to be sent any time of day or night to any list of state contacts, providing an early alert or update to foodborne illness investigations. The fax-on-demand system provides access to press releases from Federal agencies, press releases from firms about their recall, as well as other information. FDA has also instituted a 50-state conference call system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks.

FDA will modify the conference call system to involve appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-state update conference calls, in order to ensure better communication among state and federal agencies.

FSIS communicates with state departments of health and coordinates outbreak response through CDC WONDER (Internet) and both FDA and USDA maintain an liaisons at CDC to facilitate food safety activities, including outbreak investigations.

CDC has established rapid communication links with all state and territorial epidemiologists and public health laboratory directors providing rapid group electronic mail and group fax links, and

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To further strengthen our outbreak response systems

In addition, CDC, EPA, FDA, and FSIS will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

FY97 Activities

- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of CDC and FDA, HHS will designate [the Assistant Secretary for Health] to be the primary person in charge of coordination. For outbreaks that fall within the purview of USDA, the Under Secretary for Food Safety will coordinate. Both the [Assistant Secretary for Health] and the Under Secretary for Food Safety will manage outbreak responses that fall within the jurisdiction of both agencies. EPA will designate the [] as the primary person in charge of coordination when drinking water is involved.
- CDC, EPA, FDA, and FSIS, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.
- Standard procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will be developed by a group of representatives from each federal agency and from the appropriate state agencies. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness. (See "Early Warning for Foodborne Illness Surveillance" section.) The procedures will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

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Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments, and other sources. Yet, the resources available in many states and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and FSIS will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food safety program infrastructure.
- FORCG, in consultation with the appropriate outside organizations, will establish working groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.

FY98 Activities with Food safety Initiative Funds

- CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.

FOOD SAFETY FROM FARM TO TABLE:
~~A NEW STRATEGY FOR THE 21st CENTURY~~
National Food Safety Initiative
DISCUSSION DRAFT AND CURRENT THINKING
A NATIONAL FOOD SAFETY INITIATIVE

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he will request \$43 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, enhance seafood safety inspections, and expand food safety research, risk assessment, training, and education. President Clinton also directed the Secretary of Health and Human Services and of Agriculture, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world.

The President directed Secretaries Shalala and Glickman, and Administrator Browner to report back to him with recommendations in 90 days. He instructed them to explore opportunities for public/private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

We need your advice. Your perspective is essential in providing the President with a report that identifies current needs in food safety, as well as assuring the future safety of our food supply and the health of consumers. We need the perspective and suggestions of all groups who are concerned about food safety and public health to make this a successful endeavor.

The goal of this initiative is to reduce, to the greatest extent possible, the incidence of foodborne illness. The thoughts in this draft focus on the public health principle that society should identify and take preventive measures to reduce the risk of illness, and that it should focus its efforts on those hazards that present the greatest risks.

The ideas in this draft represent our preliminary thoughts on this subject. A comprehensive food safety plan, describing actions and resources necessary to achieve the goals of reduced foodborne illness, will require extensive deliberation and in-depth discussion with all stakeholders in food safety, including consumers, state, tribal, and local public health officials, industry, and members of the scientific community. This draft is intended not as a prelude to government action, but an exploration of what might result from the upcoming seminars and conferences. While this initiative focusses on reducing the incidence of microbial foodborne illnesses, we recognize that chemical contaminants are also a cause of foodborne illness, but with chronic long term effects.

BACKGROUND

The American food system provides consumers with an abundant supply of convenient, economical, high-quality, and safe food products. This system is built on the enterprise and innovative capacities of those who produce and market food in the United States, and it is driven

by the high expectations of American consumers for the foods they purchase for their families. Foodborne illness, however, still occurs in the United States. Over the last four years the Clinton Administration has developed and implemented major steps towards reinventing food regulation:

- In 1993, the Vice President's National Performance Review issued a blueprint for reinventing our nation's food safety system.
- The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) issued regulations that will require the meat, poultry, and seafood industries to follow Hazard Analysis and Critical Control Points (HACCP) procedures. HACCP, which calls for food industries to implement preventive measures of their own design, will streamline regulation of these foods, increase the industries' responsibility for and control of their own safety-assurance actions, and generally bring regulation of meat, poultry, and seafood in line with state-of-the-art scientific procedures.
- Beginning in 1994, the Centers for Disease Control and Prevention (CDC) embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.
- The Safe Drinking Water Act of 1996 includes responsible regulatory improvements to help states and water systems prevent drinking water contamination problems. Resources are provided for the first time for drinking water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

While these advances are significant, they may not be enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety programs. The food safety system is in need of reform, especially reform that builds on the preventive principles embodied in HACCP.

HISTORY OF THE FOOD SAFETY INITIATIVE

Achieving a significant reduction in the incidence of foodborne illnesses requires the cooperative efforts of public health and regulatory agencies at the federal, state, tribal and local levels, as well as all other parties responsible for and concerned about food safety and reducing the incidence of foodborne illness (i.e., consumers, industry, and academia). Partnerships - between public agencies and industry, federal agencies and state, tribal or local agencies, public agencies and academia, to name a few possibilities - will be invaluable in leveraging the resources focused on reducing the incidence of foodborne illness and enhancing communication.

Representatives of various government agencies have drafted a structure for the food safety initiative for your further deliberations. Ad hoc working groups, representing the varied perspectives of the FDA, CDC, the Department of Agriculture's Research, Education and Extension agencies, as well as the FSIS and Animal and Plant Health Inspection Service (APHIS), and the Environmental Protection Agency (EPA), have been meeting for several months to identify major food safety concerns and propose recommendations on what resources and activities are needed to have a significant impact on reducing the incidence of foodborne illness both in the short term and over the long term. The working groups worked from the premise that an effective food safety initiative must have several, interrelated components which, together, have far greater impact on reducing the incidence of foodborne illness than is possible to attain with any single component. Moreover, these elements must form the groundwork for the design and implementation of strategies to meet current needs, for continually evaluating the effectiveness of ongoing activities, and for identifying and implementing strategies to meet future needs. These elements include surveillance, coordination, risk assessment, research, inspections, and education.

This draft, which primarily defines short-term activities, describes the elements of a food safety initiative and tentatively identifies critical issues and the working groups' current thinking on preliminary recommendations. In some cases these recommendations have been included as part of the President's FY98 budget. However, no specific decision as to what will constitute the final food safety initiative, including how the strategic planning process is structured, have been made. Input from groups and individuals such as yourself, state, tribal and local agencies, consumers, industry, academia, and other stakeholders will be incorporated into the food safety initiative.

Two open public meetings of all parties interested in food safety are planned to take place in Washington, DC. The first, scheduled for March 5, 1997, is an information meeting to familiarize interested parties with the President's initiative and introduce the draft discussion document. A second meeting is tentatively scheduled for late March-early April to discuss the food safety initiative. The purpose of the second meeting is to present the key issues and solicit both comment on the preliminary recommendations and additional suggestions for inclusion in the report to President Clinton.

Using this draft as a starting point, we are asking for your perspective on how best to enhance the safety of the food supply and reduce foodborne illness. Please consider the following questions in guiding your response, considering both the immediate future and the long term:

Questions:

1. Have the critical elements of an effective food safety initiative been identified? Are there others? What are they?

2. Have the appropriate issues within each element been identified? If not, what additional issues should be included?
3. What are the priorities among the issues identified or added to each element of the initiative?
4. What steps should be taken to begin to resolve issues within each element of the initiative?
5. What are the responsibilities of various stakeholders in working toward resolution of the issues?
6. How can we better utilize public/private partnerships to reduce foodborne illness?
7. How should food safety activities be better coordinated across the federal agencies, accommodating the needs and perspectives of state and local agencies, consumers, industry, and academia, to maximize the effect of available resources?
8. How do we ensure and measure the effectiveness of the food safety initiative?
9. How should the evaluation be structured so that the results of the early evaluation can be factored into the strategic planning process?
10. What recommendations do you have for the structure of the strategic planning process?

The comments, suggestions, and information from these meetings will be used in preparing the report to the President.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC HEALTH PROBLEM

Foodborne infections remain a major public health problem. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Hospitalization costs alone for these illnesses are estimated at over \$3 billion a year. Costs for lost productivity for 7 specific pathogens have been estimated to range between \$6 billion and \$9 billion. Total costs for all foodborne illnesses are likely to be much higher. These estimates do not take into account the total burden placed on society by the chronic, often life-long consequences caused by some foodborne pathogens.

Additional, important safety concerns are associated with the greater susceptibility to foodborne infections of several population groups. These include persons with lowered immunity due to HIV/AIDS, those on medications for cancer treatment or for organ transplantation, as well as pregnant women (and their fetuses), young children, and elderly persons. Patients taking antibiotics, or antacids, are also at greater risk of infection from some pathogens. Other groups who may be disproportionately affected include persons living in institutional settings, such as hospitals and nursing homes, and those with inadequate access to health care, such as homeless persons, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Sources of food contamination are almost as numerous and varied as the contaminants themselves. Bacteria and other infectious organisms are pervasive in the environment. *Salmonella enteritidis* enters eggs directly from the hen. Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables in the field. Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage. Seafood may become contaminated from agricultural and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments. Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animal. Milk, eggs, seafood, poultry, and meat from food-producing animals may become contaminated due to contaminated feed, misuse of veterinary drugs, or poor farming practices, including production and harvesting activities, or disposal of solid waste on land. Foods may become contaminated during processing due to malfunctioning or improperly sanitized equipment; misuse of cleaning materials; rodent and insect infestations; and improper storage. Foods may become contaminated in retail facilities and in the home through use of poor food handling practices.

Although many hazards threaten the safety of our food, certain foodborne hazards are of particular public health concern, and would be targeted for immediate attention by this initiative. Studies have shown that the following microbial pathogens are the predominant foodborne pathogens. They are: *Salmonella* species, *Campylobacter jejuni/coli*, *Escherichia coli* O157:H7 and other related strains; the parasites *Toxoplasma gondii* and *Cryptosporidium parvum*; and the Norwalk virus.

The microbial pathogens listed above, and discussed in greater detail below, may give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. The microbial pathogens described below are not listed in order of importance or severity.

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immuno-compromised, the very young, and the elderly. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Animals used for food production are common carriers of salmonellae, which may subsequently contaminate foods such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. Between 128,000 and 640,000 of these infections are associated with *Salmonella enteritidis* (SE) in eggs. Over the past decade, more than 500 outbreaks have been attributed to SE with over 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium, *Campylobacter*, is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 170,000 and 2.1 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (2 closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, perhaps as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

***Escherichia coli* O157:H7**

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools, and has been associated with HUS. HUS is a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure, and is particularly serious in young children. *E. coli* O157:H7 has its reservoir in cattle, but the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. It has been estimated that approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with an estimated 6 deaths. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak, in the Fall of 1996 in 3 western states and British Columbia, was associated with unpasteurized apple juice and sickened 66 people and caused the death of one child.

Toxoplasma gondii

T. gondii is a parasitic protozoan. It has been estimated that 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Otherwise healthy adults who become infected usually have no symptoms, but may get diarrhea. Pregnant women who become infected during pregnancy may pass the disease to their fetuses. In infants infected before birth, fatal results are common. Should the infant survive, the effects of infection are typically severe. The disease can also be serious in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables may contribute to these infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in otherwise healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among persons with weakened immune systems. The largest recorded outbreak of cryptosporidiosis was a waterborne outbreak that occurred in Milwaukee, Wisconsin in 1993, affecting over 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths attributed to *Cryptosporidium*. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. This outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* is found in feces of infected mammals and has been transmitted through contaminated water and food.

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease, that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multi-state outbreak of viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis, involved seventy ill people and was associated with the consumption of raw oysters. In 1992, another outbreak occurred which included 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Ensuring the safety of food is one of the core functions of government. It is carried out by a system that, while generally successful in protecting the public, can be confusing for its complexity and diversity. Authority is divided among federal, state, and local governments; and the private sector also plays an important role. From the farm to the consumer's dinner table, the responsibilities can be summarized as:

- On the farm, food is regulated by state agencies supported principally by the EPA, which acts to ensure that pesticides are approved for safe use, by the FDA, which oversees use of drugs and feed in milk- and food-producing animals, and by APHIS, which is concerned with food-animal disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and ground waters, and solid waste to land, all of which could contaminate growing and process waters or grazing land.
- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by the FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA has fewer than 700 inspectors and analysts devoted to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose 8,000 inspectors are present in 6,500 slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.
- Food being transported in interstate commerce is subject to federal and state regulation, although that area has received little attention in the past. USDA's FSIS and HHS's FDA have jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether

regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to harmful bacteria during transportation.

- The importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.
- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) are generally regulated by states and local health authorities, and FDA publishes the *Food Code*, which consists of model recommendations for safeguarding public health when food is offered to the consumer. Recommendations are developed by consensus of state government representatives at the Conference for Food Protection. FSIS and FDA are working with states to update the *Food Code* in light of the changing retail and food service environment and emerging food safety issues, especially with regard to meat, poultry, egg products, and seafood. The Conference for Food Protection serves as one forum for fostering cooperation among federal, state and local governments in the oversight of food products and the conditions under which they are produced, processed, transported, stored, and handled through retail sale or food service to the consumer.
- National standards for drinking water are set by EPA, and enforced generally by local public water authorities; FDA establishes complementary standards for bottled water.
- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their source, and control outbreaks. FDA or FSIS are called in when a link to a regulated food is suspected.
- In the home, consumers also have a responsibility for proper handling and storage of food, as consumer mishandling contributes to many cases of foodborne illness. As a result of this knowledge, FSIS promulgated safe handling labels for raw meat and poultry products.
- Other responsibilities related to food safety include research into the cause and transmission of foodborne illness, and education on treatment and prevention of foodborne illness. These responsibilities are carried out by the USDA, FDA, CDC, EPA, the National Institutes of Health, other federal components, and the states. Basic biomedical research on pathogenic organisms is conducted at the National Institutes of Health. The federal government also supports related research in universities. The private sector supports research within its own laboratories and in universities.

THE FOOD SAFETY SYSTEM MUST BE PREPARED FOR THE 21ST CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early years of this century. It must be modernized. The current system is inadequate to properly identify, track, and prevent food-related illness and to prevent future cases from occurring. State and federal resources are not closely coordinated and duplication of effort is not uncommon. In 1981, FDA inspected food firms every 2-3 years, but can now visit those plants, on average, only once every 10 years. Our understanding of some disease causing organisms is so limited that our ability to protect the public health is seriously constrained. Food processors, restaurateurs, supermarket managers, and consumers often don't understand the threat from foodborne pathogens and the methods available to prevent and control them.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

There are many causes of foodborne illness, many points at which foods can become contaminated, and numerous factors that make some groups of people more susceptible than others. Needless to say, no single preventive measure will ensure the safety of all foods. However, a number of practical preventive steps can be taken immediately to reduce the incidence of many foodborne infections.

Any initiative designed to improve the safety of the food supply should focus on the hazards and foods that present the greatest risks to public health, should emphasize development and implementation of preventive controls of those risks, and should seek opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders. This prevention-control concept is HACCP, a science-based, state-of-the-art process for building safety into the production, handling and storage of food. HACCP is being implemented by the meat, poultry, and seafood industries with FSIS and FDA regulatory oversight. The application of such preventive controls to other types of food may be important to protecting food in the years to come.

Under this initiative, the federal government, in concert with state and local governments would conduct research and risk assessments to determine how foodborne illnesses occur and can be prevented or controlled; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focussing on the use of safe practices. These issues, and our current thinking about them, are described below.

A NEW “EARLY WARNING SYSTEM” FOR PUBLIC HEALTH SURVEILLANCE

Background

The primary goal of the American system of public health is to prevent disease before it occurs. While prevention of all disease may not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs a more effective early warning system that can catch outbreaks early, preventing illness and death. Such a system will also advance our understanding of foodborne illness and further our prevention efforts. In his January 25 radio address, the President announced a new national early warning system for foodborne illness that he is funding in his FY98 budget.

Preliminary Problem Identification

Surveillance and investigation of foodborne disease are powerful tools to detect new foodborne disease challenges, to determine what the specific food sources are, and to learn how best to keep the foods from becoming contaminated in the first place. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and among federal partners. Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to expand the existing Active Foodborne Disease Surveillance Network (sentinel sites) to identify, investigate and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and deaths.

Current Thinking

The federal government in cooperation with state and local health departments is proposing to take the following steps to establish a new national early warning system for, and enhance surveillance of, foodborne disease. These changes will result in an improved system for detecting and reporting foodborne illnesses and outbreaks that will enable public health agencies to rapidly put into place measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including HACCP systems, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

1) Enhance and expand the Active Foodborne Disease Surveillance Program

CDC, FDA, and USDA currently support five food sentinel sites at state health departments to

track cases of foodborne infections and to determine the sources of the most common ones. The existing sites should be strengthened, and the number of "enhanced" sites should be increased to 7 in FY 97, and to at least 8 in the following year. The sites and federal food safety agencies should be electronically linked together to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional states will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

2) Enhance early detection of foodborne disease nationwide

In addition to establishing enhanced food sentinel sites, an early warning system would require improved early detection of foodborne disease in additional states in FY 98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among bacteria, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks, and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome.

3) Modernize public health laboratories

CDC should provide resources and training to upgrade public health laboratory capabilities in the Active Surveillance sites and in other states so that they can rapidly identify a broad range of foodborne infections including new parasitic and viral pathogens, and can use new techniques of DNA "fingerprinting." CDC would work with states to develop, standardize, and transfer those methods. These new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

4) Create a national electronic network for "fingerprint" comparison

CDC should fund a new computer network and database system that would capture bacterial "fingerprints" in a national database, linking CDC, FDA, USDA, and states that have this new capacity as well as the federal laboratories into a new national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California, which would suggest to public health investigators that a product distributed in both California and Washington may be contaminated with the organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, surveillance of contamination levels in foods, in animals used for food, and in their feed is important to control and prevent foodborne diseases, and to monitor the measures that reduce the risk of exposure. Therefore, to make the "early warning system" fully operational, and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

5) Increase national surveillance for antimicrobial resistance of foodborne pathogens

CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and USDA should take similar steps for bacterial samples from food-producing animals and food products, in a way that permits these data to be compared. CDC, FDA and USDA should develop standard procedures for sharing necessary information, and for responding to increases in resistance, or other "red flag events" such as the discovery of an important new resistant bacterium.

6) Enhance oversight of animal feeds and feedstuffs for the impact of drugs and other therapies in food animal populations and pathogens

FDA may consider increasing monitoring of animal feed processing to determine the nature and extent of pathogen contamination and the impact of control strategies on pathogen reduction in animals.

COORDINATION

Background

At the federal level, there are four agencies charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC at HHS, FSIS at USDA, and EPA. While CDC's primary responsibility is to work with state and local health departments to identify and investigate sporadic cases and outbreaks of illness, FDA, FSIS, and EPA have the additional responsibility of taking regulatory action against the suspect products, or those who contaminate the air, land, or waters used to produce the food product. Which regulatory agency gets involved depends on the type of food involved, with FSIS having primary jurisdiction over meat, poultry, and egg products, FDA over all other foods including shell eggs and EPA over water and pesticides. While each agency has clearly defined areas of responsibility, most outbreaks of foodborne illness involve more than one agency.

In addition, investigations of foodborne illness usually begin at the community or state level. These illnesses may cross jurisdictional boundaries and may be linked to foods or food ingredients that were processed or produced in another state or by international trading partners, necessitating the involvement of federal agencies. Federal involvement is also necessary when contaminated foods from the same sources may be in grocery stores, restaurants, and homes in other parts of the country. Companies responsible for affected products also have a critical role to play as many product recalls are voluntary.

In most outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and implementation of control measures through consultation, diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and state authorities. For large or multi-state outbreaks, federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

Preliminary Problem Identification

Although significant coordination already occurs among the federal and state agencies, the mere fact that more than one agency is involved in any one outbreak of foodborne illness can cause some confusion. Many times a joint effort is hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Current Thinking

Improved coordination among the federal agencies, between federal and state agencies, and

among the various state agencies would enhance the level of public health protection, make the best use of interagency collaboration, and avoid duplication of effort.

1) Improve federal/state coordination in the management of response to foodborne illness

A Foodborne Outbreak Response Coordinating Group made up of representatives of the federal and state agencies charged with responding to outbreaks of foodborne illness should be created to coordinate the investigation and response to significant outbreaks of foodborne illness. The overall goal of this group should be to ensure that a coordinated and professional response, with all governmental resources pulling together, is undertaken to effectively investigate and respond to foodborne illness. The group should determine jointly each agency's responsibilities during the various phases of outbreak investigations, and who would play the role of spokesperson for each phase or component of an outbreak. In addition, the group should coordinate communications and decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks. The coordinating group should also meet several times a year to review its work and the response to outbreaks.

Each participating agency could fund and enhance programs that provide opportunities to exchange employees, on a temporary basis, among federal agencies and between federal and state agencies. Such an exchange would facilitate coordination by sharing expertise and providing an opportunity to better understand the various roles each agency plays in an investigation of a foodborne illness.

2) Improve federal/state coordination in the management and response to foodborne illness

Better coordination between federal and state agencies and among the various state agencies would speed the identification and subsequent control of foodborne illness and the removal of the contaminated foods from the distribution chain.

In order to improve coordination, the federal agencies can sponsor a national meeting with state and local officials to develop recommendations on how to better coordinate the overall government response to foodborne illness.

For example, one specific issue that is discussed in FDA's FY98 budget is the occurrence of *Salmonella enteritidis* in layer hens and improved monitoring of the hens and liquid bulk egg products (before pasteurization) for contamination. The federal agencies should work to establish a federal/state cooperative program to solve this problem.

3) **Enhance the basic infrastructure for foodborne illness surveillance and coordination at state health departments**

The epidemiology offices and laboratories within state health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments and other sources. Yet, the resources available in many states for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the states' effectiveness. As a result, outbreaks may go undetected or are never investigated.

This problem could be rectified by making sure that, given an assessment and cataloguing of available state resources, states are provided support for foodborne disease surveillance programs and assistance to better investigate outbreaks of foodborne illness.

RISK ASSESSMENT

Background

It is a basic public health tenet that public resources devoted to reducing risks should be in proportion to the toll they take on human health. Risk assessment is the tool best suited to set priorities among public health risks. Furthermore, risk assessment is a requirement for any science-based system of preventive controls. Indeed, risk assessments and evaluations of alternative risk management strategies are often carried out for major federal regulations. Pursuant to the USDA's Reorganization Act of 1994, USDA is required to conduct risk analyses for all major regulations. Such evaluations ensure that risk reduction strategies are cost effective and promote the maximum net benefit to society of efforts to reduce foodborne illness. Sound risk assessments, including bacterial, parasitic, and viral food contaminants, are also critical to World Trade Organization treaty negotiations, which require that U.S. food safety standards be based on scientifically valid measures derived through risk assessment.

Preliminary Problem Identification

Risk assessment's objective is to characterize the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require a substantial amount of specific information on the hazard and on the exposed population to provide meaningful information for those making risk management decisions. Even for chemical hazards, for which risk assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk, and mathematical "models" of chemical action or of the way that the body deals with a chemical.

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed data such as pathogen behavior in numerous foods under hundreds of conditions, and information about especially sensitive populations, such as children.

Current Thinking

This initiative's risk assessment activities would focus on developing better use of data and better models to inform surveillance plans, HACCP-based prevention strategies for process control systems and for food inspections, and research programs to fill critical food safety information gaps.

1) Establish a risk assessment consortium

All federal agencies with risk management responsibilities should establish jointly a new

consortium at which federal agencies can set collective priorities for risk assessment research and collective priorities and strategies for the further development and implementation of risk assessment and risk management. The consortium should be established at the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and the University of Maryland.

The consortium should focus federal research on developing data for risk assessments, focused and applied specifically to address the scientific, risk-based goal of preventive control that is the central principle of this food safety initiative.

Research supported and conducted through this initiative should cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures. Data and methods developed in response to the Safe Drinking Water Act Amendments of 1996, for example, will be relevant to food safety evaluations.

2) Develop better data and modeling techniques to assess exposure to microbial and chemical contaminants, including animal drug residues, through the food supply

Risk assessment of foodborne illness is dependent on accurately estimating the quantity of a toxin or pathogen ingested by the consumer (i.e., exposure assessment). This initiative would address the numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research should be conducted in: incidence and prevalence of microbial pathogens and chemical hazards in food; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; intake data regarding food consumption patterns of the general population and sensitive subpopulations; and specific data on food vehicles of sporadic and epidemic disease. Research using biomarkers should be pursued. Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure and effect are difficult or impossible to obtain.

3) Develop dose-response assessment models for use in risk assessment

Research is needed to estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality. For bacterial hazards, the World Health Organization's Expert Consultation on the Application of Risk Analysis to Food Standards Issues (FAO/WHO, March 1995) refers to these steps as "hazard characterization."

BIOSCIENCE RESEARCH

Background

Currently, one of the most critical needs in food safety research is for techniques to more rapidly and accurately identify and characterize foodborne hazards. FDA, CDC, EPA, and the USDA's Research, Education, and Economics agencies (the Agricultural Research Service, the Cooperative State Research, Education, and Extension Service) conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food.

Preliminary Problem Identification

New pathogens, some of them foodborne, have emerged over the last 10 years. Many of these organisms can not be easily detected, or detected at all in foods. Other microorganisms, previously thought to be innocuous, have emerged as more virulent. Just because organisms are present at levels that can not be easily detected, however, does not mean that the organisms can not cause human illness. Newly recognized pathogens are causing serious disease outbreaks. Foodborne pathogens are increasingly overcoming time-tested controls, such as heating and refrigeration, and are developing new virulence and new ways to evade our immune defenses.

Current Thinking

Effective control of foodborne pathogens requires that prevention be targeted at high-risk foods and at high-risk points in their production and distribution. These interventions ideally are guided by risk assessment, for which all too often we have insufficient data. Research is needed to support HACCP implementation, to enable verification that critical control points in HACCP systems are working, and to target the data gaps that hamper risk assessment. Among the data gaps and information needs identified here are numerous opportunities for collaboration and resource leveraging among federal agencies, the private sector, and universities.

1) Improved detection methods

As stated above, many foodborne pathogens cannot be easily detected, or detected at all in foods. Methods need to be developed, validated, and implemented for rapid testing of very low levels of *Campylobacter*, *Salmonella*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, Norwalk virus and naturally occurring toxins in food animals, in agricultural and aquaculture products, animal feeds, and processed food products. Some research efforts may initially focus on *Campylobacter*, because those foodborne infections are so prevalent and may lead to chronic diseases (Guillain-Barré syndrome); also methods to isolate and identify this pathogen are time-consuming and expensive. Research could be coordinated with EPA's efforts to develop better test methods and assessments of health effects from *Cryptosporidium* and other

contaminants in drinking water. Improved methods are needed for identifying foodborne pathogens, including emerging pathogens, in clinical specimens and to subtype known foodborne pathogens.

2) Understanding antimicrobial resistance

Microorganisms can become resistant to antimicrobial agents and conditions that have been traditionally relied on to eliminate or prevent the growth of foodborne pathogens, but have become insufficient to prevent breakthrough of newly emerging pathogens. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food safety safeguards such as heat or cold, low pH, high salt, and disinfectants and to elucidate factors in animal and plant production systems and processing environments that influence the development of resistance. This research will lead to the identification of food production and processing practices that are likely to permit pathogen contamination or proliferation and will provide guidance in the modification of traditional techniques or the development of new techniques to prevent or control pathogen growth.

3) Understanding antibiotic drug resistance

Pathogens in food-producing animals may become resistant to drugs partially due to improper use of the drugs, particularly antibiotic drugs, in those animals. One possible way to deal with this problem might be to adjust the required period of drug withdrawal prior to slaughter. For example, studies should be conducted to explore possible changes to "withdrawal time" requirements that could reduce transfer of resistant pathogens with minimal disruption to industry production practices. In addition, industry in collaboration with federal agencies could determine the basis for the ability of microorganisms to rapidly adapt to changing environments and, together, develop animal production and treatment mechanisms to minimize this adaptive ability.

4) Prevention techniques: Pathogen control, reduction, and elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to store. Food animals may carry pathogens, but remain healthy themselves, complicating controls at the point of slaughter. Animal feed and drinking water can be "hidden" but significant sources of contamination. Possible research recommendations to address these problems for *Salmonella*, *Campylobacter*, *Toxoplasma*, *Vibrio*, *E. coli* O157:H7, *Cyclospora*, *Cryptosporidium*, and Norwalk virus in all food products are the following (to be carried out in conjunction with universities and the private sector):

- Develop drugs and other therapies to prevent initial colonization.

- Develop new methods to reduce or eliminate contaminants from animals and plants before slaughter or harvest.
- Develop new disinfection methods and equipment and systems modifications for processing and production plants, and wholesale and retail outlets.
- Develop new methods of surface decontamination of fresh fruits, vegetables, meat, poultry.
- Develop heat-based and/or other disinfection methods for seafood, meat, eggs, produce, and animal feeds.

5) **Food handling, distribution, and storage**

Food production and processing often occur thousands of miles apart. Transportation systems for live animals, fresh produce, and packaged foods offer many opportunities for contamination, such as heat, cold, and other stresses that make animals and plants more susceptible to infection, and cross-contamination from the vehicle itself. Possible research recommendations include the following:

- Investigate immune system "biomarkers" of stress that might indicate predisposition to infection during transport.
- Develop in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

INSPECTIONS

Background

Inspection of commercial food processors is an integral part of the food safety assurance system. Inspections are carried out by federal, state and local authorities, with state and local officials focusing primarily on restaurants, supermarkets and other retail establishments. At the federal level, consistent with legal mandates, FSIS has carcass-by-carcass inspection in meat, poultry, and slaughter plants while they are operating, and continuous inspection in meat, poultry, and egg-product processing plants--in all, about 8,000 inspectors for 6,500 domestic plants and for all imported meat, poultry, and egg products. FDA does periodic, random inspections of all other food processing plants--less than 700 inspectors and analysts for 53,000 U.S. plants and for all other imported foods.

Preliminary Problem Identification

At FDA, the number of inspections has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. The result is that an FDA-regulated plant gets inspected by FDA, on the average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, the inspectional coverage of imported foods has dropped as well, as the same number of import inspectors are now inspecting almost twice as many imports as just five years ago. Certainly FDA is finding greater problems, e.g., the number of products recalled for life-threatening microbial contamination has increased almost 5-fold since 1988 and inspectors are finding more hazardous conditions in the plants they inspect. FSIS is faced with a similar challenge of continually providing the most effective inspection program with limited resources and growing threats to food safety.

Current Thinking

Scientists and other food safety experts have concluded that the most effective and efficient mechanism for assuring that food processors identify and control hazards that could threaten food is the application of the HACCP concept of built-in preventive controls. FDA has begun to implement HACCP for the seafood industry, and FSIS for the meat and poultry industries; FSIS intends to publish an ANPR requesting comments on HACCP systems for egg processing plants, and FDA plans to work with the food industry, as it has in a pilot program over the last 2 years. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, the following preliminary recommendations are being made.

1) Enhance development of HACCP procedures

FDA is considering whether and how to implement HACCP throughout the non-meat/poultry food industry for all appropriate food commodities. It is recognized that staged implementation, by commodity, might be necessary because of resource limitations. To ensure that HACCP is being properly implemented, FDA should conduct inspections and provide necessary training and outreach activities. FSIS will continue development of a HACCP-based inspection system. FSIS plans to conduct a public meeting and then subsequent field trials to gather data to support future decisions on designing new inspection procedures in a HACCP environment.

2) Upgrade FDA's food inspection program

FDA has included implementation of seafood HACCP in its FY98 budget request. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food safety procedures in effect, FDA must improve its inspection capabilities, so that the highest risk food plants (such as seafood) are inspected at least once per year. To maximize the joint federal/state role in inspections, development of new partnerships with the states may be considered, that focus on coordinating the inspection coverage and preventing duplication of effort.

FSIS and FDA may consider expanding and re-focussing existing cooperative agreements under which plants producing both meat and non-meat foods are inspected solely by FSIS inspectors, who have been trained in FDA inspectional standards. FSIS inspectors are already in these plants; their presence could be better utilized to maximize use of federal resources.

FSIS and FDA are considering whether and how to regulate the transportation of meat, poultry, seafood, eggs and other foods in order to safeguard the public from pathogenic microorganisms, as reflected in the ANPR published on November 22, 1996.

3) Enhance federal/state inspection partnerships

Additional federal/state partnerships can ensure improved coordination between the federal food safety agencies and state regulators for the training of state inspectors in federal food safety standards, as well as provide the states with equipment and technology for the rapid sharing of inspection results and for a national database for the monitoring of all food inspections. This information sharing would help both federal and state regulators make inspections more effective and efficient.

FDA may consider establishing a process for certifying private laboratories that would be authorized to test samples of food products for contaminants. This may embody a similar process currently being discussed by a coalition of industry, private laboratories, professional

associations, and accrediting bodies with input from federal agencies. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

4) Enhance inspectional coverage of imported food, to address the problem of rising imports and FDA's inability to provide adequate inspections of them

FDA should develop more Mutual Recognition Agreements (MRAs) with foreign countries, under which both countries agree to inspect each other's food exporting firms under equivalent procedures for ensuring safety. Once such MRAs are in place, FDA could better focus its import inspections on foods coming from countries with the least reliable safety standards.

EDUCATION

Background

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Educational efforts have already been made at the federal level. For example, FDA has a website which offers information on many food safety issues, has established a 24-hour seafood hotline, and has published brochures on such topics as food safety advice for persons with AIDS and posters on such topics as listeria in soft cheese. USDA has taken similar steps through its Cooperative Extension network, its Meat and Poultry Hotline, and by requiring safe handling instruction labels for meat and poultry products.

Preliminary Problem Identification

Despite these efforts, and the work that states, consumer groups and the food industry have done in this area, foodborne illness still occurs from a lack of knowledge of the risks involved at all stages of food preparation. For instance, choices consumers make about how they handle food prepared at home and whether they eat food that increases the risk of foodborne illness can have a significant impact on the incidence of foodborne illness. Studies show, for example, that 53% of the public eat food with raw eggs, 23% eat undercooked hamburger, 17% eat raw clams and oysters, and 26% do not wash their cutting boards after using them for raw meat or poultry.

Foodborne illnesses have also been traced to commercial food establishments. For example, many food establishments do not know that the pooling and undercooking of eggs can increase the risk of *Salmonella enteritidis*. Currently, a much higher percentage of those who receive their food in an institutional environment are victimized by the more serious consequences of foodborne illness. For example, during 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of these *Salmonella* outbreaks were caused by *S. enteritidis*. *S. enteritidis* also resulted in more deaths than any other pathogen with 85% of these deaths occurring among residents of nursing homes.

Producers of animals used in human foods production and veterinarians treating such animals also need education in food safety practice. Drugs used to treat these animals are not always used appropriately, and can be purchased over the counter by non-veterinarians and mis-used, resulting in harmful residues in meat and milk, decreased effectiveness of these drugs, and increased antimicrobial resistance.

Finally, those responsible for the transportation of food are often unaware of unsafe practices that result in the contamination and mishandling of food during shipment.

Current Thinking

Understanding and practicing proper food handling procedures from farm to table would significantly reduce foodborne illness.

1) Improve consumer education

An alliance including industry and consumer groups should mount a comprehensive food safety awareness campaign for consumers, highly focused on messages and tactics targeted to the general public and to special populations such as high-risk consumers. The campaign should be centered around an easily recognized symbol or catch phrase and should include a national print and broadcast media campaign and incorporate food safety messages into school curricula. An emphasis should be placed on multilingual activities to ensure the widest coverage.

Innovative methods for sharing information related to food handling behaviors should be developed in order to reach larger audiences. As part of this effort, a National Food Safety Education Alliance of industry, consumer, trade, state and local food protection agencies, and academic organizations focused on changing unsafe food handling practices should be convened. Research should be conducted to determine effective methods of providing information and evaluation of educational programs. A national clearinghouse should be established to provide consumers and food safety educators with food safety information.

2) Improve retail, food service, and institutional education

A highly focused campaign should be developed to change food workers' unsafe food preparation behaviors. A multilingual approach should be developed. An alliance of federal, state, and local health agencies, as well as private parties, should be formed to develop education efforts on food safety issues. Activities of the alliance should include educating retail food service workers about the safe handling perishable food product provisions in the 1997 *Food Code*.

In addition, guidelines should be developed by USDA and the states for retail and food service operations which process meat and poultry products to train state level inspectors to identify hazards at the retail level. Efforts should also be undertaken to educate the retail, food service and institutional industries in order to increase the use of HACCP principles.

3) Improve veterinary and producer education

Development and implementation of a program could be considered to educate producers of animals for human food consumption, veterinarians, state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality assurance programs. The

program could entail regularly scheduled training sessions, including satellite teleconferences, educational symposia, and presentations at producer and practitioner meetings. Guidelines and educational materials could also be developed and disseminated through a national clearinghouse to food producers and the veterinary medical community.

4) Improve industry education in the transportation area

Government agencies could form an alliance to develop educational materials and train food transportation vehicle owners and operators and food processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature controls, prior cargoes, and sanitation methods. Training and education for state and local health and transportation authorities could also be conducted so they can apply this information during inspections of food processing facilities and transportation vehicles in their jurisdiction.

A STRATEGIC PLAN FOR REDUCING FOODBORNE ILLNESS OVER THE LONG TERM

Background

The broad issues of a sustainable safe food system include, among other issues, improving the infrastructure for rapid identification and response to outbreaks, improving coordination among all food safety participants in numerous aspects of prevention and response, and developing a strategic, long-range research agenda. Stakeholders include food producers and manufacturers, consumers, academic institutions, representatives from the food service sector, including retail, restaurant, and institutional food service settings, veterinary and medical professionals, and federal, state, and local public health and agricultural officials.

Preliminary Problem Identification

Making the necessary improvements in the food safety system will not be easy. Because so many lines of authority must be crossed, so many new working relationships established, and so many fundamental changes in infrastructure made, the current system must be “reinvented.” For example, the federal government needs to develop a long-term, coordinated research agenda to truly address research needs to support a fundamentally improved food safety system, and strategies for developing such an agenda would need to be developed through such a planning process. Extensive dialogue will be required among the many stakeholders in various regions of the country to agree upon priorities, strategies for achieving change, and a process for achieving change.

Current Thinking

A significant activity proposed as part of this food safety initiative is the creation of a process that facilitates the participation of all stakeholders in discussing the issues and setting an agenda for consideration of fundamental change in the food safety system.

A contract could be established with an independent organization to bring together all major stakeholders for discussion of fundamental changes to the present food safety system. A major purpose of this strategic planning exercise would be to identify changes that should be made to the present organizational and procedural structure that would bring about permanent improvements in efficiency and coordination. Dialogue groups could be established to develop a strategic plan. Opportunities for input could include symposia held in geographically dispersed sites to encourage stakeholder participation.

Documents developed from the deliberations and recommendations of these symposia could be the focus of further discussion during a series of open meetings. The product of this series of

dialogues, symposia, and hearings could form a report, which would provide the outline necessary for targeting needed structural changes in the federal/state food safety system.

FOOD SAFETY INITIATIVE

Outbreak early -- response

VP - REGO report

- USDA 6,000 plants /8,000 inspectors; FDA 53,000 plants, 700 inspectors
- single food agency
- preventive controls (HAACP)
- scientifically sound, risk-based inspection system
- automated reporting system on inspection frequencies
- uniform regulatory action to give inspectors enforcement authority
- administer all research functions

Progress

- HAACP for meat, poultry, seafood; consumer and producer confidence/dialogue

Reconciliation -- FDA/HHS -- that we needed to do more... asked for \$90 million -- scaled back to \$43 million. Do the most important things -- not a comprehensive piece.

- What can we commit to now
- How we frame the next step...

January 25 Radio Address (stmt, directive, fact sheet)

Took credit for our accomplishments

Announced \$43 million FY 1998 budget request

11.5 M. early warning system;
23 M FDA
8.5 M USDA

Asked agencies to recommend additional measures -- surveillance, coordination, inspection, risk assessment, research, and education. Look for ways to work in partnership with the private sector.

Discussion Draft (bring)

released in late February
public meetings-- working sessions focusing on six areas
response

Manley Molpus -- GMA
John Cady -- NFPA

FY 97 Activities
FY 98 Activities w/food safety insurance funds
Long term activities.

SHORT TERM GOALS

- Get our appropriations -- strengthen seafood and produce programs
- Take next steps w/in budget commitments
- Define longer term agenda -- maintain progress /good will

REPORT

Key actions

- Reiterate **surveillance** enhancements in 98 budget. Add specificity -- case-control study of hepatitis A --- lay groundwork for control strategy; -- Gulf Coast *Vibrio Vulnificus* surveillance strengthened. 2 sites in 97
3rd in 98
high tech capacity w/98 funds
- Low hanging fruit -- **education partnership** -- do food handling guidelines similar to dietary guidelines; training for food handlers
- **Interstate Outbreak response coordinating group** -- standing group of people in Fed agencies and state and local gov't; goal is to have single, coordinated response with states; will have a leader (sticking point); **two teams under it -- standing early outbreak detection and evaluation team** -- experts at CDC, state epidemiologists, FDA, USDA -- quickly and accurately identify outbreaks. Second team -- **outbreak response team** -- vary from outbreak to outbreak (FDA, USDA lead).
- **Risk Assessment** -- interagency group setting collective priorities across agencies; focus on microbial contamination; dose response methods.
- **Inspections** -- strengthen seafood inspections; FDA HACCP rule for juice products; FSIS proposed HACCP rule for egg products; FDA/FSIS cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruits and vegetables; Imports -- FDA system for certifying/accrediting private laboratories to test samples.

— Research —

Strategic Questions —

— hard low spec order —

— Small

- Mer v/ Sally - v. specific recommendations
-

Public - Private

- Education partnerships

Outside budget requests

- specified 2 sites in 97
1 site in 98
-
- Hepatitis A study - CDC
- Oyster surveillance - stepped up

Handful are regulatory

- ~~Apple juice~~ HACCP juice and egg products
- ~~Apple~~

HACCP expansion to other areas

- Coordination

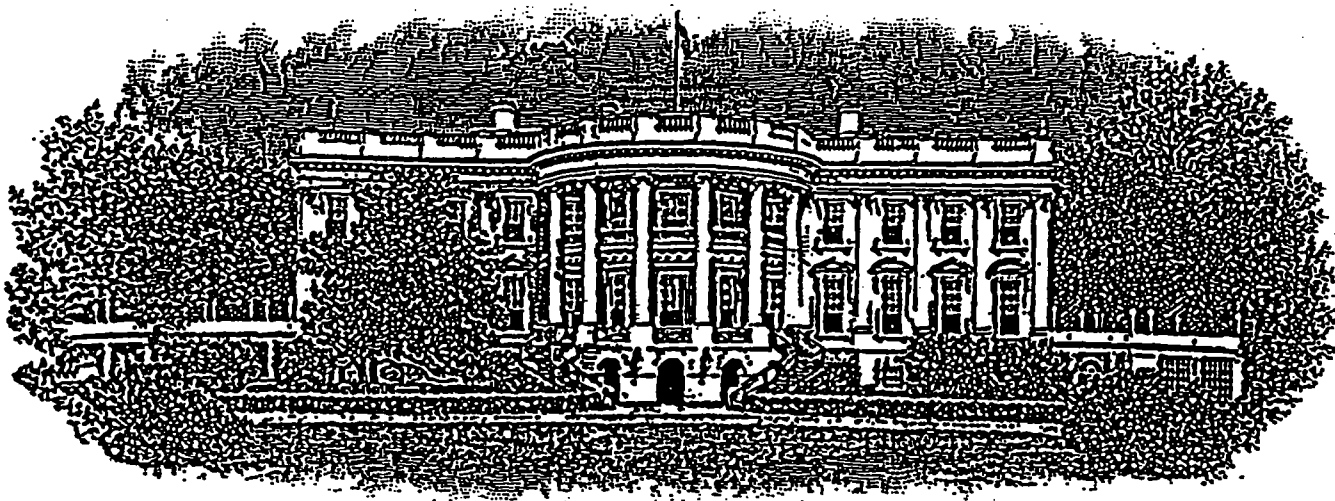
Strategic Planning / Next Steps process.

- Education
- Research
- Risk assessment
- Inspection
- Coordination
- Surveillance

producer groups (acceptance, e.g. produce)

consumer groups (practicality/trust, e.g. education o.k.)

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Joan Mondshein

FAX NUMBER: 720-9600

TELEPHONE NUMBER: _____

FROM: Elizabeth Drye

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: Here's the earlier coordination
draft.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), FSIS (at USDA), and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to interstate outbreaks. When an interstate outbreak occurs, all of the affected entities must work together to prevent deaths and minimize illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in identifying and investigating sporadic cases and outbreaks of illness and to prevent additional cases from occurring. FDA, FSIS, and EPA have the additional responsibility of taking regulatory action against the suspect products, or wastes such as animal manures which have the potential to contaminate the air, land, or waters used to produce the food product. The type of food affected determines which regulatory agency has jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of most outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a primary role. Identification and investigations of foodborne illness usually begin at the community or state level. States are responsible for protecting the health of their residents. Federal agencies become involved when illnesses cross state borders or when foods or food ingredients that were processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated foods from the same sources have been distributed to grocery stores, restaurants, and homes in other parts of the country.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and implementation of control measures through consultation, diagnostic assistance, and recommendations for control measures. In some instances on-site assistance is requested by the local and state authorities. For large or multi-state outbreaks, federal agencies play a critical coordination role to assure consistency of approach and implementation of needed control measures.

Companies responsible for affected products also have a critical role to play. Most food product recalls are voluntary. Federal and state agencies can benefit from industry's expertise about contaminated products and their distribution patterns.

Problem

Changes in how food is produced and distributed has led to a growing number of regional and national foodborne outbreaks. Although significant coordination already occurs among the federal, state, and local agencies, better coordination is needed to meet these new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Breakdowns in communication can cause confusion that can lead to public harm. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation, putting the public health at risk.

Recommendations

While state and local health departments will remain the primary organizations responsible for the detection and the conduct of investigations of outbreaks confined within their borders, federal, state, and local governments should improve coordination of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort.

1) Improve outbreak containment through better federal/state/local coordination of the evaluation of and response to foodborne illness

CDC, EPA, FDA, and USDA will establish an intergovernmental group to coordinate the investigation and response to interstate outbreaks of foodborne illness. In addition to the four federal agencies, the Foodborne Outbreak Response Coordinating Group (FORCG) will include representatives of state and local agencies charged with responding to outbreaks of foodborne illness. The group will serve four purposes.

First, FORCG will oversee the federal response to an outbreak of foodborne illness.

Second, FORCG will establish an early outbreak detection and evaluation team consisting of federal, state, and local foodborne disease experts. This team's primary task will be to ensure that the cause of an outbreak is established quickly and accurately. It will use information generated by the new national early warning system to identify potential problems and real outbreaks. The team will also develop algorithms and protocols for evaluating the evidence about the cause of an outbreak.

Third, FORCG will establish an outbreak response coordinating team for each outbreak that requires a federal response. During an outbreak, this team will ensure a coordinated and rapid response to contain the outbreak. The team will be modeled on the Incident Command System that is used by other federal emergency responders such as the Forest Service and the Department of the Interior to manage forest fires and the Federal Emergency Management Administration. The team will determine jointly each agency's responsibilities during the various phases of

outbreak investigations, and will designate a single spokesperson for each phase or component of an outbreak. In addition, this team will coordinate communications and decisions about appropriate actions during outbreaks and appropriate follow-up to prevent similar outbreaks.

Fourth, FORCG will review and evaluate outbreak response and the work of the two outbreak teams. FORCG will undertake these reviews in consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

FY97 Activities:

- CDC, EPA, FDA, and USDA, in consultation with representatives of state and local governments, will establish the Foodborne Outbreak Response Coordinating Group.
- The Foodborne Outbreak Response Coordinating Group will establish the Early Outbreak Detection and Evaluation Team and the Outbreak Response Coordinating Team.

2) Enhance state and local infrastructure for foodborne outbreak detection, evaluation, and response coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments, and other sources. Yet, the resources available in many states and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and USDA will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne disease surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities:

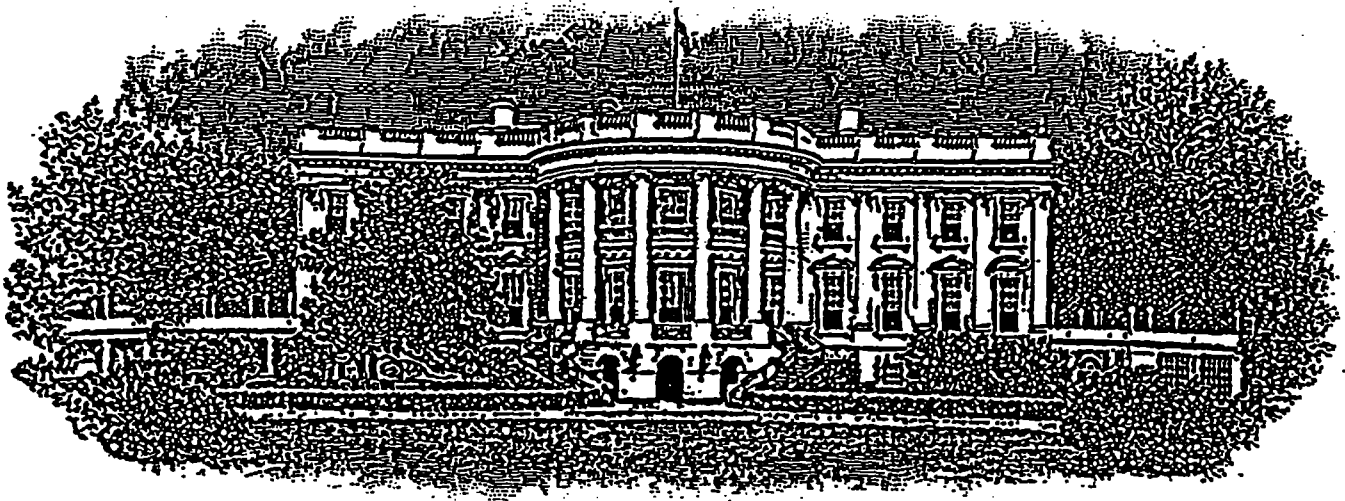
- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Department's of Agriculture, will begin a nationwide audit to catalogue the existing state and local food safety program infrastructure.
- FORCG, in consultation with the appropriate outside organizations, will establish working

groups consisting of federal, state, and local officials to develop recommended procedures for outbreak response coordination at the state and local level.

FY98 Activities with Food Safety Initiative Funds:

- CDC, EPA, FDA, and USDA should assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.
- CDC, EPA, FDA, and USDA should establish a program to improve outbreak coordination through the exchange of employees among federal, state, and local food safety programs and within state and local programs.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Kitty Higgins

FAX NUMBER: 6-2983

TELEPHONE NUMBER: _____

FROM: Elizabeth Dwyer

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: Here is latest draft of exec summary —
newsworthy items marked with "*". Bruce talked to
Rahn — they agreed we should submit sched request — priority
is Tuesday w/VP or this Friday w/POTUS (unlikely). Christa
Robinson at DPC is drafting now and will get to Liz for
your joint signature if you'd like.

- Have a good trip.
- Liz and I will set up 4:00 pm Wed mng.
on coordination

Food Safety report
ref: 10/1/97

Executive Summary
-- DRAFT --

In his January 25, 1997 radio address, President Clinton launched a new initiative to improve the safety of the nation's food supply. The President announced he would request \$43 million in his 1998 budget to fund a nation-wide early warning system for foodborne illness, increase seafood safety inspections, and expand food safety research, training, and education. The President also directed three Cabinet members -- the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- to identify further steps to improve the safety of the food supply. He directed them to develop these next steps working with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days.

Four agencies in the Federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); the Department of Agriculture (USDA); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the president, the agencies have explored ways to strengthen systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

This report presents the results of that consultative process. It outlines the steps USDA, HHS, and EPA will take ^{million} this year to reduce foodborne illness, and spells out in greater detail how agencies will use the \$43 in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

The actions in this report build on previous Administration steps to modernize our food safety programs and respond to these emerging challenges. In 1993, the Vice President's National Performance Review issued a strategy for reinventing food safety. The report noted that our inspections system had a limited ability to detect microbial contaminants. As a key recommendation, the report urged the wide-spread adoption of preventive controls. Specifically, the report urged implementation of hazard analysis and critical control point (HACCP) systems to ensure food manufacturers identified points where contamination is likely to occur and implement process controls to prevent it. ✓

Acting on this recommendation, the Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulation to modernize the nation's meat and poultry inspection system for the first time in 90 years. The Early Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. And additional actions outlined in this

report will expand the use of HACCP principles throughout the food industry.

KEY ADMINISTRATION ACTIONS

Enhance Surveillance and Build an Early Warning System

As the President announced in January, the Administration will build a new national early warning system to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, the Administration will:

Enhance Surveillance, Expand from 5 to 8 the number of "FoodNet" active surveillance sentinel sites. Existing sites are ~~in~~ New sites will be ~~in~~ CDC will also increase surveillance activities for certain specific contaminants; for example, CDC will begin a case-control study of hepatitis A virus to determine the proportion of cases due to food contamination and strengthen surveillance for *Vibrio* in Gulf Coast oysters.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify the source of infectious agents and with additional epidemiologist and food safety scientists to trace outbreaks to their source;

Create a national electronic network for rapid fingerprint comparison — agencies will equip the sentinel sites and other state health departments with DNA "fingerprinting" technology, and will link sites together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Further Food Safety Education

Foodborne illness remains prevalent throughout the United States in part because food preparers and handlers at each stage of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food safety techniques from farm to table would significantly reduce foodborne illness. The Administration -- working in partnership with the private sector -- will, among other things:

Establish a Public-Private Partnership for Food Safety Education — FDA, USDA, and CDC will work with the food industry, consumer groups and the states to launch a food safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food safety slogan and several standard messages. Industry has pledged \$500,000 to date to support the Partnership's activities and plans to raise additional funds.

Educate professionals and high risk groups -- agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail and food service workers in safe handling practices.

Improve Responses to Foodborne Outbreaks

*No California, Oregon,
Minnesota, Georgia and
Connecticut
2 list
8 sites*

At the Federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, and USDA's Food Safety and Inspection Service (FSIS) and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To more quickly identify an outbreak's cause and ensure a rapid response, agencies will

* (if we
make it
real)

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group
[still under discussion]

Strengthen the infrastructure for surveillance and coordination at state health departments

Improve Risk Assessment

Risk assessment methods help characterize the nature and size of the risk to human health associated with foodborne hazards and assist regulators in making decisions about controlling those hazards. To improve risk assessment capabilities, agencies will:

Establish an inter-agency risk-assessment consortium to set priorities and guide overarching federal risk assessment research related to food safety;

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table.

Develop new Research Methods

Today, many pathogens in food or animal feed cannot be identified, and others have developed resistance to time-tested controls such as heating and refrigeration. The agencies will focus research immediately to:

bold
- Develop rapid, cost-effective tests for the presence of pathogens, such as Salmonella, Cryptosporidium, E.Coli 0157:H7, and hepatitis A virus.

bold
- Enhance understanding of how pathogens become resistant to food preservation techniques and antibiotics

bold.
- Develop technologies for prevention and control of pathogens.

Increase Inspections

The agencies will pursue several strategies to increase inspections for higher risk foods; the agencies will *among other things*:

- **Implement Seafood HACCP**-- FDA will add seafood inspectors using new FY98 funds to implement new seafood HACCP regulations, and will work with the Commerce Department to better integrate the Department's voluntary seafood inspection program with FDA's program.



- propose new regulations for fruit juices (FDA); FDA will also propose, among other things, to require the use of HACCP for juice products. USDA will consider whether to propose HACCP regulatory options for egg products.

- Improve coverage of imported foods ... [to be added]

The volume of foods being offered for import into the U.S. has almost doubled in the past 5 years without a concomitant increase in inspection and analytical staff. The overall effect is a lowering of the level of inspection and sampling of imported foods. FDA will

- Expand its program to develop mutual recognition agreements (MRAs) with trading partners. Under MRAs, the trading countries ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.

- Initiate a federal/state communication system covering imported foods

- Provide technical assistance to countries whose products are implicated in a public health problem, such as a foodborne illness outbreak.