One Hundred Years of Shellfish Regulation

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Introduction

Shellfish, as a food category. has a distinctive history of regulation. Unlike meat and poultry, shellfish has never been subject to 100% mandatory product inspection by the federal ∼zovernment. This absence of inspection does not reflect a regulatory decision that shellfish pose little risk to humans. On the contrary– the available statistics, although incomplete, indicate that seafood illness made up about 5% of all foodborne illness cases between 1978 and 1984: More importantly. 53% of these seafood illness cases were caused by molluscan shellfish. The chance of contracting illness from finfish is only one in five million, but a serving of shellfish presents a risk of one in 250.∼ Although illness can be caused by either biological pathogens or chemical contaminants in seafood, it is usually the naturally occurring pathogens that are responsible for human illness. Pathogens enter water from domestic sewage or pass from humans or other warm-blooded animals to seafood during subsequent handling.[4] To prevent contamination, then. regulation must address both the quality of the harvesting beds and the subsequent handling of shellfish.

Both the pre-harvest and the post-harvest aspects of shellfish regulation contain inherent difficulties. As time passes, ensuring the quality of harvesting beds becomes more arduous:

firstly, because of a general increase in pollution; and secondly, because when the amount of a natural resource decreases, its value increases– making illegal harvesting of shellfish more profitable, less deterrable, and more frequent.[5] This explains why human illness has increased

GAO, Seafood Safety: Seriousness Of Problems and Efforts to Protect Consumers, Rep. No RCED-88-135 (August 10,1988).

Rep. No. RCED-88-135 at 2.

David S. Cloud, *Food Safeiv: House 'Surf and Turf Fight Dooms Fish Inspection,* 48 Cong.Q. 43(1990).

Rep. No RCEDS8-]35.

Id.

C\ en though many states, such as New York, now harvest fewer clams. Furthermore, lack of enforcement regarding harvesting shifts the responsibility for assuring that shellfish are safe and healthful... [to the] individual baymen.[0] Shellfish diggers tend to be independent workers who have taken advantage of the low cost of entry into an industry that still relies on manual labor.[7] Because the baymen have not formed a cohesive industry, regulations often cannot overcome each individual's incentive to exploit community resources.[8] The government thus struggles to enforce pre-harvest sanitation requirements.

The industry that handles shellfish after harvest also presents a challenge for regulation. Shellfish plants are mostly small and aged facilities, seasonally run, and... many lack modem day technology.[9] Seafood is one of the few remaining food groups still a wild-caught flesh food that frequently must be harvested under difficult conditions and at varying distances from processing, transport and retail ~ Agents simply cannot enforce regulations when they cannot even reach the vessels that act as processing factories.[11] And yet, despite all of the factors that detract from seafood safety, aggressive controls over shellfish are noticeably absent from the history of rei~ulation. Even today, the Food and Drug Administration (FDA) samples less than 1% of our domestic seafood and less than 30/0 of our imported seafood.[1]

Margaret Becker, New York Sea Grant Institute State University of New York and Cornell University, *The 1982 Shel~fish-ReIated Disease Outbreak In New York State: Agency Response and Ineraction,* Rockefeller Institute Working Papers, Feb. 1983 at 9.

Id at 6, 9

8 *Id.* at 33.

40 FedReg. 25916, 25919 (1975).

60 FedReg. 65096, 65097 (1995).

Consideration of Meat, Poultry and Seafood Inspection in the United States: Heari,ii~

Before the Subconim. on Livestock, Dairy & Poultry of the House Comm. on Agriculture, 1 04th

Cong., 2d Sess. (1996) (statement of Dr. Michael Friedman, Deputy Commissioner, Operations.

FDA) [hereinafter Dr. Michael Friedman].

Whereas the FDA inspected food firms every two to three years as of 1981, today the FDA visits the same firms only once every ten years! FDA,USDA, EPA & CDC, Discussion

Attempts to compose shellfish regulations meet with several obstacles. Any legislation will necessarily have targeted and intense effects, because the shellfish industry exists in discrete geographic areas where it dominates the local economy. On Long Island, for instance,' clamming is the third largest industry: it brings $100 million dollars per year to the island economy and provides work for more than 6,000 baymen and 1,100 shippers)[4] Overzealous legislation could economically destroy the shellfish industry, but if legislation is too hesitant, contaminated products may destroy the shellfish market. Insufficient safeguards have already left their mark. New York's share of the national clam market fell from 50% to less than 30% in a decade," and, in 1990, overall consumption of fish in the United States declined 15 percent- at least in part because of decreased consumer confidence in the quality of the fish we eat.[16]

One could accurately summarize shellfish regulation as a conglomeration of federal agencies. Federal participants include: the Department of Health and Human Services, which

Draft, *Food Safety From Farm to Tabie.- A New Strategy for the 21st Century* (Feb.21, 1997), *available at* http://vm.cfsan.fda.gov/—dms/fs-draft.html [hereinafter *Food Safety]*

This paper frequently offers New York State, and Long Island in particular, to illustrate issues of shellfish regulation. There are many reasons why New York stands out in a historical analysis. New York State at one time harvested the most hard clams in the nation; in 1976, Suffolk County alone produced 58% of the total U.S. landings of hard clams. (SCPD, infra note 14, at 2). Long Island has active shellfish groups and innovative programs dealing with shellfish safety. The State Department of Health has had the most extensive foodborne illness disease surveillance program in the nation since 1980 (COSMA, *iP?fra* note 72, at 5). One group of Baymen developed the Green Seal program, a self policed tagging system. However, the relationship between the Baymen and state agencies has not always been smooth, nor has shellfish safety be∼n achieved. In 1985 the Department of Health believed that New York was implicated more often than any other state as the source of shellfish, or as a possible source of shellfish, in more of New York's health-related outbreaks and more incidents than any other state. *Id.*

Rep. No. HR.D-84-36 (1984). *See also* Becker, *supra* note 6, at 9. In 1976 Long Island reached its maximum landing of hard clams: nine million pounds. Clamming also creates a secondary market in marine related jobs such as sale and repair of boats and equipment. Suffolk County Planning Dept (SCPD), *Strategies and Recommendations for Revitalizing the Hard Clani Fisheries in Suffolk County New York* 2 (1987)

Rep No HRD-84-36 (1984).

136 Cong Rec S2228-04 (daily ed. Mar. 7, 1990).

contains the FDA and the Centers for Disease Control and Prevention;'[7] the Environmental Protection Agency;'[8] the U.S. Department of Agriculture; the U S. Department of Commerce, which contains the National Marine Fisheries Service and the National Oceanic and Atmospheric Administration;'[9] the National Shellfish Sanitation Program; and the Fish and Wildlife Service. Efforts to remedy seafood contamination have produced unexpected relationships such as the FDA's interagency agreement with the USArmy to develop analytical methods of detecting seafood toxins)∼U The United States even reaches out to foreign governments, establishing compacts to exchange research on the sanitary conditions of seafood. Once one adds state agencies to this federal conglomeration, the complexity of shellfish regulation becomes quite evident. In New York, not only does the federal government have authority, but also towns claim title to the bay bottom, counties have jurisdiction, and the state's power extends to three miles offshore.[2]' This historical survey reveals just how our intricate system of overlapping agencies has evolved; more importantly, it reveals the difficulties particular to the shellfish industry–difficulties that ensure that the battle over shellfish regulation will continue well into the next century.

The CDC's primary responsibility is to work with state and local health departments to identify and investigate sporadic cases and outbreaks of illness *Food Safety, supra* note 12.

s EPA is responsible for water and air quality that can affect whether fish are safe to eat.

and its establishes limits for pesticides. Dr. Michael Friedman, *supra* note 11.

For example. the FDA works with the NOAA in order to close federal waters if oil spills, toxic blooms or other phenomena threaten seafood safety. Paula Kurtzweil, *Critical Steps Thitard Sqfer Seafood,* FDA Consumer Nov-Dec. 1997. The NOAA also runs a voluntary fee-for-service inspection program for seafood processors. Dr. Michael Friedman, *supra* note 11
Rep. No RCED-88-135.

David R. Zimmerman. *The Cop on the Boat. Tightening the Net Against Unsaje Shellfish.* FDA Consumer Feb. 1986 at 29 [hereinafter *The Cop on the Boat].*

Chapter One

Basic Facts About Shellfish Diseases

Shellfish are more problematic than other fish products because shellfish will acquire any contaminants that exist in the surrounding water– and usually at higher concentrations Shellfish obtain their food and oxygen by filtering particulate matter from seawater.[2] They are called filter feeders, because a muscular siphon, the neck, sucks water into the animal and through its digestive system where the food and oxygen are removed.[23] In this process, shellfish can store up bacteria or viruses. The bacteria or viruses found in the water do not harm the shellfish, but they do remain within the animal for a long time– even after harvest. Aggravating the shellfish's susceptibility to contamination is its habitat. The natural breeding ground for shellfish is an estuary: where a river meets the sea. Unfortunately, these estuaries are also prime locations for cities, which means that shellfish waters are more likely to be polluted than offshore waters.:[4]

Another reason that agencies subject molluscan shellfish to special safeguards is because unlike crustacean shellfish *(e.g.,* crabs, shrimp and lobsters), molluscan shellfish are generally eaten whole and raw. For federal regulatory purposes, the word shellfish has traditionally included oysters, clams and mussels. Regulations exclude scallops even though they, too, are filter feeders. The regulations explain that frequently, only the scallop's adductor muscle is eaten; this reduces the risk of illness because viruses and bacteria are not accumulated in the adductor muscle. The latest regulations actually include scallops in their definition of shellfish, but they

Carol Ballentine, *Pollution Narrows Shellfish Harvest,* FDA Consumer, Feb. 1985 at 10 [hereinafter *Pollution Narrows].*

-' New York State Department of Health, *Shellfish Related Illness* (pamplet on file with author).

Roger W. Miller, *Getting Hooked on Seafood Safety,* FDA Consumer, June 1991. at 7

contain an exception stating that the regulations do not apply if only the adductor muscle is eaten. Thus, the regulations continue the policy of defining shellfish according to the risk they present, rather than their biological category.

Consumption of shellfish can cause illness for several reasons. Most commonly, a shellfish causes illness because it is carrying either bacteria or viruses. Bacterial pathogens might include Vibrio cholerae, Vibrio parahaemolyticus, Vibrio vulnificus, or Clostridium botulinum. Viruses include hepatitus A and the Norwalk virus. There are shellfish toxins such as paralytic shellfish poison, amnesiac shellfish poison and demoic acid poison.[26] Parasites and related worms can also infect the shellfish.~[7] Some bacteria and viruses are introduced into the water by humans, through pollution, for example. Other pathogens occur naturally and cannot be prevented Unfortunately, current science lacks a practical method to detect most viruses– whether in water, shellfish or patients. For most reported outbreaks, agencies cannot identify an etiologic agent; they merely hypothesize that a virus caused the illnesses7[8] Furthermore, although it is understood that improper food handling causes bacterial infection, such post-harvest conduct may or may not cause virus-induced infection)[9] Thus, information regarding seafood viruses is limited.

-. New York State Department of Health, *Shellfish Related Illness.*

-~ FDA and CDC estimate that there are approximately twenty cases per year of poisoning

caused by the presence of these toxins in shellfish. Final Regulatory Impact Analysis: Procedures
for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg

65096-01 (1995) (codified at 21 C F R. §123, §1240).

U.S Dept HI-IS, CFSAN, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, *available at* Bad Bug Book, http //vm.cfsan fda gov/—mow/sea-ill.html. [hereinafter Bad Bug Book].

Centers for Disease Control & Prevention, *Multistate Outbreak of I ThaI Gastroenteritis Related to Consumption of Qvsters– Louisiana, Maryland, Mississippi, & North ('arolina, 1993* 42 Morbidity & Mortality Wkly. Rep. 49 (Dec. 17, 1993)

Herbert L. DuPont, M.D., *Consumption of Ral4.' She gfish- Is the Risk Now Unacceptable*~ 3 14 New Eng J.Med. 707, 708 (1986).

Nevertheless, agencies have compiled a good deal of data on the more common illnesses caused by shellfish. The following catalogue divides seafood illness into four categories. The first tv∼o categories are bacterial and viral illness linked to pollution. The remaining two subheadings describe unpreventable, or naturally occurring, bacteria and viruses.

I Bacterial illness linked to pollution *Thphoid*

One bacterially- caused illness is typhoid fever. Although it was once the most common shellfish-borne disease, no documented cases of typhoid fever have been reported due to eating shellfish since 1954. so Typhoid can be transmitted from sewage or from improper handling by an infected person. In 1939, for example, 87 cases of typhoid were attributed to fecal contamination of a storage area by a typhoid carrier.[3]'

Gastroenteritis

Gastroenteritis is an inflammation of the lining of the stomach and the intestines. Symptoms such as abdominal cramps, diarrhea, nausea, vomiting, headache, fever and chills may occur from 4 to 48 hours after eating food. Many different bacteria and viruses can cause gastroenteritis, including Norwalk virus and Vibrio vulnificus

3(1 Carol Ballentine, *Weighing the Risks of the Rcm' Bar,* FDA Consumer. Sept. 1986 at 2 I [hereinafter *Weighing the Risks].*

Manual of Operations, Part I, National Shellfish Sanitation Program, 1995 at C-8 [hereinafter NSSP Manual 1995].

I i *hrio pLlrahaemolyticus*

Vibrio parahaemolyticus is an example of bacteria that will cause gastroenteritis. Both pathogenic and nonpathogenic forms of the bacteria exist. The bacteria will multiply in improperly refridgerated seafood. Major outbreaks have occurred in the United States during the warmer months of the year.[3]: For example, on August 23, 1997 the U.S. Department of Health and Human Services released a statement advising consumers to check the source of any fresh oysters purchased within the preceding week, because warm weather in the Pacific Northwest had raised the amount of V parahaemolyticus in shellfish to unsafe levels. Approximately forty illnesses were reported in California and Washington, with one hundred more in British Columbia. The Pacific Coast Oyster Growers Association voluntarily halted shipments of live oysters, and the FDA advised consumers to fully cook oysters in order to kill the bacteria.[33]

Thrio cholerae

Vibrio cholerae is the bacterium that causes cholera, an illness that can range from mild diarrhea to fatal dehydration. While no major outbreaks have occurred in United States since 1911. there were several cases between 1973 and 1991 affiliated with consumption of raw or improperly cooked shellfish. The cases suggest that the V. cholerae organism has reappeared in the U.S. marine and estuarine environment Environmental studies confirm that strains of cholerae currently exist in temperate estuarine and marine waters.[34]

Bad Bug Book. *supra* note 27. at chapter 9.

Judith Foulke, *HHS News: Statement Advising Consumers About Oysters From the Pacific Northwest,* U S. Dep't Health & Human Services, *available at* http:// www.fda.∼ov/ bbs topics! NEWS! NEW00586 html

Bad Bug Book *supra* note 27. at chapter 7.

2 Viral illness linked to pollution *Hepatitis A*

One virus-caused illness is hepatitis A, a disease of the liver. Hepatitis A virus can get into the body from eating raw or even steamed shellfish that were harvested from polluted waters. Symptoms may appear from fifteen to fifty days after eating the food, and they include fever, nausea, vomiting and abdominal discomfort, followed by an enlargement of the liver. Severe cases can cause liver damage and death. From 1960 through 1963, over 1,000 people were diagnosed with hepatitis A illness after eating oysters and clams. ~ Only very high heat will destroy the hepatitis A virus.[36]

Norwalk

The Norwalk virus acquired its name because it was first discovered in 1968 during an outbreak of gastroenteritis linked to drinking water in Norwalk, Ohio. Today we have identified Norwalk virus as responsible for 181,000 illnesses each year.[37] Shellfish are contaminated either by infected food handlers or by boats dumping raw sewage overboard. Symptoms of Norwalk virus infection trace the symptoms of gastroenteritis; persons usually recover within two to three days without serious or long term health effects.[38] Scientists have discovered many calciviruses that are related to the Norwalk virus, including a virus found in oysters that caused six illnesses in Florida in 1980.~~ In 1982, 1,017 people in New York State became ill within seven months due to

Weighing the Risks. supra note 30.

3c. Carol Ballentine, *For Oyster and Clam Lovers, The Water Must Be Clean,* FDA

Consumer, Oct. 1984, at 24 [hereinafter *Water Must Be Clean].*

Centers for Disease Control, Office of Communication Division of Media Relations, *CDC Fact Sheets. Nont'alk-like I ?ruses,* Nov. 28, 1997, *available at:* http *I!* www.cdc.gov/od/oc /medialfact/norwalkv. html

Id.

9

Norwalk- contaminated shellfishi[3] In 1993, several oyster-related gastroenteritis outbreaks occurred. Seventy-three persons in Louisiana and about 130 others in Maryland, Mississippi and North Carolina, became ill.[4'] Another multistate outbreak occurred in January 1995 In a 1996 outbreak, the infected oysters were traced to a malfunctioning sewage system.

3. Naturally Occurring Viruses *Paralytic Shell Poison fish*

In addition to human pollution, shellfish can be infected by viruses that occur naturally in the water. One naturally-occurring virus is paralytic shellfish poisoning (PSP)– also called Red Tide. Red Tide is caused by a one-celled algae-like microorganism of the genus Gonyaulax~ Gonyaulax appears in coastal waters of Canada, New England, California and Alaska. The microorganism produces a nonprotein poison, fifty times more potent than the paralytic poison curare.[43] When the gonyaulax blooms in shellfish harvesting waters, the shellfish become poisonous because they ingest the toxins during filter feeding. The term Red Tide developed because the water sometimes contains plankton (dinofiagellates) in such numbers as to discolor the water~ Unfortunately, the shellfish may be carrying the plankton several days before the water changes color[45] and actual discoloration is relatively rare'~ The PSP toxin acts on humans

- *Weighing the Risks, supra* note 30, at 2 1-23. *Id.*

Centers for Disease Control and Prevention, *Multistate Outbreak of Viral Gastroenteritix Related to Consumption of Qysters– Louisiana, Maryland, Mississippi, and North Carolina, 1993,* 42 Morbidity & Mortality Wkly. Rep. 49 (Dec. 17, 1993).

Carol Ballentine. *Red Tide,* FDA Consumer, Dec. 1980- Jan.1981, at 30 [hereinafter *Red lide].*

Id.

Miller, *supra* note 24 at 10.

Id.

Red T~'de, supra note 42 at 32.

within minutes, and there is no antidote. The toxin causes tingling in the lips, burning sensations and numbing. Death from respiratory failure can occur in three to twelve hours. Treatment consists of diuretics and emetics to empty the gastrointestinal tract, and artificial respiration. Although the minimum amount of toxin needed to cause illness is unknown, death has been caused by ingestion of only 450 to 1,100 micrograms of the toxin. In a recent outbreak the contaminated clams contained 4,000 micrograms of toxin per 100 grams of meat; where clams weigh about 10 grams, a person could receive a lethal dose from eating only three clams.[47] No amount of cooking can completely deactivate the toxins that cause PSP.[48]

Most attempts to prevent PSP have achieved only limited success. Because toxin levels can rise dramatically almost overnight, even routine collection of shellfish samples will not ensure the safety of harvesting waters.[49] States can only respond to illness reports when harm has already been done. For example, California quarantined all mussels during an outbreak in 1927, but not before 102 illnesses and six deaths occurred. The presence of the bacteria and dinoflaggelates that cause PSP are linked to water temperature, such that less bacteria appear when the water is colder. Afier the presence of Red Tide increased steadily through the nineteen-eighties, California banned sports harvesting of mussels from May I to October 3 1. In 1984, California mussels showed unusually high levels of toxin early in the year, prompting the state to impose its harvesting ban two months early, in March.

In 1972 the first PSP epidemic on the east coast occurred. In that year, nearly one hundred dead black ducks and gulls were discovered in the Plum Island, Massachusetts estuary. Scientists who performed autopsies on the birds found mollusk shells in the birds' intestines. Soon

Id.

Water Must Be Clean, supra note 36.
Red Tide, supra note 42.

thereafier, Gonyaulax was discovered in Gloucester, Massachusetts water. The State Department of Health quickly banned all shellfish harvesting, but despite the department's quick reaction, t'∼entv-six people became ill with PSP. Since then, Massachusetts has had problems with (ionvaulax almost every year

4 Naturally Occurring Bacteria I ∼ *brio idnificus*

Vibrio vulnificus is a free-living bacterium, which, because it occurs naturally in marine waters, cannot be avoided by eating oysters from clean water. V. vulnificus poses particular difficulties because it appears in many varieties– some harmful, some not– and it is found in low levels in all water) The single consolation is that bacteria within the Vibrio species can be killed by cooking[5]' If ingested, V.vulnificus can cause primary septicemia[5] or gastroenteritis. It can also cause infection by directly contaminating open wounds, such as lacerations incurred through shellfish cleaning.[53] The data on illness caused by V vulnificus is limited. Between 1975 and 1985 the Centers for Disease Control (CDC) recorded only twenty-five reported cases (including twelve mortalities) of V. vulnificus primary septicemia due to eating raw oysters or other

Proposals for the Establishment of a Federal Seafood Inspection Program, Hearings Before the Subcomm. on Dept Operations, Research & Foreign Agriculture of the House Comm. on Agriculture, 101st Cong., 2d Sess. 49, 209 (1990) (statement of James Benson, Acting Commissioner of Food and Drugs) [hereinafter James Benson]. For example, V. vulnificus is present in up to 50% of oyster beds with water conditions of temperature> 68 F [>20C] and salinity of **K** 16 parts per thousand. These conditions are normal for the Gulf of Mexico during warm months. Centers for Disease Control, I *'ibrio I ∼dnificus Infections Associated With Eati;it∼' Raw Oysters– Los Angeles,1996,* 45 Morbidity & Mortality Wkly. Rep. 29 (July 26. 1996)

Water Must Be Clean, supra note 36.

- Primary septicemia is blood poisoning.

Water Must Be Clean, supra note 36. *See also* CDC, I *ibrio* I *'ulnificus Infections Associated with Raw Oyster Consumption– Florida, 1981-1992,* 42 Morbidity & Mortality Wkl∼ Rep. 21, (June 4, 1993).

seafood.[54] However, regional surveillance in four states along the Gulf Coast indicates a higher annual incidence for V. vulnificus infections: at least 0 6 per one million persons, and a case-fatality rate of 22%.~ In fact, the Florida Department of Health and Rehabilitative Services recorded 125 cases of V. vulnificus, in which 35% were fatal, between 1981 and 1992.56 The FDA's estimation that twelve to twenty-six reported cases occur annually, with fatalities averaging between five and twelve, thus seems fairly accurate.[57] In a 1995 brochure the FDA warned consumers that 40% of V. vulnificus infections from raw oyster consumption are fatal.[58]

There is evidence that V. vulnificus presents a special risk to people with liver disease, such as cirrhosis or hepatitis.[59] Also at risk are people with hemochromatosis, iron disorder, diabetes, stomach problems such as low stomach acid, cancer, immune disorder such as HIV, and long-term steroid use (as for asthma and arthritis)i'[4~ For people with at-risk medical conditions, consumption of Vibrio oysters can cause sudden chills, fever, nausea, vomiting, blood poisoning and death within two days. FDA estimates that there are about nine million at-risk people who should not eat raw or under-cooked molluscan shellfish.[6'] In order to alert the at-risk population,

Pollution Narrows, supra note 22. at 13.

W.C. Levine, P.A. Griffin & Gulf Coast Vibrio Working Group, *Vibrio Infections on the Gulf Coast. the Results of a First Year of Regional Surveillance,* 167 J. Infect Dis. 479 (1993).

Centers for Disease Control and Prevention, *Vibrio Vulnificus Infections Associated with Raw Qyster Consumption– Florida, 1981-1992,* 42 Morbidity & Mortality Wkly. Rep. 21, (June 4, 1993).

However, about one third of these illnesses are from bacterial entry into the body from wounds– usually experienced by commercial fishermen. *Seafood Safety, Hearings on The She llfish Safety Act, H.R. 1412 Before the Subomm. on Fisheries Management of the House Comm. on Merchant Marine & Fisheries,* 103d Cong., 1st Sess 9-30, 5 1-124 (1993) (statement by Thomas J Billy, Dir, Office of Seafood, CFSAN) [hereinafter Thomas J. Billy].

U.S. Food & Drug Admin., Brochure: *If you eat raw oysters, you need to* ***knOw...,*** July 1995, *available at.* http://vm.cfsan.fda. gov/—lrd/oyster. html

Pollution Narrows, supra note 22, at 13.

6' *If you eat raw oysters, you need to know..., supra* note 58.

Thomas J. Billy, *supra* note 57.

FDA/CFSAN, *Guidance Documents for Trace Elements in Shellfish, available at* http /1' vm cfsan.fda gov/ ∼-frfYguid-sf html

the FDA has attempted to establish a liasion with medical and health communities. The Office of Health Affairs acts as one link between FDA and medicine; it is campaigning to include computerized printouts that describe the risk of Vibrio vulnificus within any prescription for an at-risk condition.6

Chapter Two

Current Methods Used to Discover Contaminated Shellfish

Today, agencies determine the safety of shellfish according to the cleanliness of the water. States test water samples for fecal coliform bacteria, which are called indicators. Fecal coliform bacteria are commonly found in the intestines of warmblooded animals, and their presence indicates that there is sewage in the water.[63] Agencies worry about the presence of even domestic sewage because such sewage can carry and transmit more than one hundred different viruses to shellfishf'~ Sewage also enhances the ability of bacteria and viruses to survive in seawater. Sewage can enter the water via effluent from sewage treatment plants, cesspools, or even storm sewer runoff from streets befouled by dogs.[65] For example, on Long Island, bacteria historically entered the bays through waste produced by duck farms[66]

The National Shellfish Sanitation Program (NSSP) Manual establishes acceptable microbiological standards for shellfish growing waters. If waters fail to meet microbiological standards; shellfish harvesting from that area is generally forbidden. Because the supply of unpolluted waters is continually shrinking, we have been forced to develop exceptions to this rule; for example, shellfish harvested from contaminated areas may be marketed if they are relayed or depurated.0[7] Relaying entails transplanting shellfish from polluted areas to approved areas under the theory that the shellfish will pump clean water through its system– at a rate of 15-20 gallons

Pollution Narrows, supra note 22, at 11.

Id at 13.

6' *The Cop on the Boat, supra* note 21, at 31.

o *Id*

Daniel A. Hunt, *Microbiological Standards for Shellfish Growing Waters– Past, Present and Future Utilization,* 69 Proceedings of the National Shellfisheries Association 142 (1979)

per dayoS∼∼ and will eventually be cleansed. Similarly, depuration involves submerging shellfish in tanks of clean water in order to flush out pathogens. The length of time required to purge contaminants from the shellfish is affected by the amount and type of contaminants, the species of shellfish, temperature and various environmental factors.[69] Microorganisms such as viruses may survive for up to four months within oysters that are submerged in clean water.[7]0 Nevertheless, both relaying and depuration provide a general benefit of removing shellfish from uncertified waters, thus removing the temptation to poach there.[7'] Depuration is not a simple solution, however. It requires strict surveillance and enforcement to ensure that shellfish designated for depuration are indeed depurated and that the entire system from harvest to depuration to market is not short-circuited. ı' Also, there is a fear that transplanting shellfish may bring Gonyaulax organisms to new marine areas where PSP had not previously existed.[73]

The NSSP Manual sets forth five possible classifications of a growing area: approved. conditionally approved, restricted, conditionally restricted, and prohibited.[74] Areas are approved if the sanitary survey and marine biotoxin surveillance data indicate that fecal

68 *The C'op on the Boat, supra* note 21, at 3 1.

69 NSSP Manual 1995 at D-l.

One author fears that the standards for depuration are erroneously based on the rate of loss of bacteria from contaminated shellfish which probably do not apply to viruses. DuPont, *supra* note 29, at 708. Studies demonstrate that clams contaminated with virus retained 50-909/a of the virus after being released in unpolluted water and kept there for up to two months! Under bacterial monitoring, depuration may be required for as little as 72 hours. *Id*

The Cop on the Boat, supra note 21, at 31; SCPD, *supra* note 14, at 25. Relayed clam beds also create a positive incentive because when transplanted beds are later opened to diggers, they will increase the size of the legal harvest.

Coastal Ocean Sciences and Management Alternatives (COSMA) & Livmnn Marine

Resources Institute, *Raw Shellfish and Public Health: Are There Acceptable Alternatives to a*

Cooking Requirement to Reduce Health Risks to an Acceptable Level? Working Paper No. 15.

June 27, 1985, at 9. [hereinafter COSMA]. SCPD, *supra* note 14, at 25.

NSSP Manual 1995 at C-7.

material, pathogenic microorganisms, poisonous and deleterious substances are not present in the area in dangerous concentrations. 05 Conditionally approved waters are waters that are subject to intermittent and predictable pollution events. Waters may be subject to intermittent pollution because of seasonal population, the sporadic use of a harbor facility or the success of a wastewater treatment facility. Under conditional approval the state sets the conditions during which shellfish may not be harvested; for example, when the river.., reaches 3.66 meters.. the area will be closed.[76] A restricted classification means that waters are subject to a limited degree of pollution, but shellfish are safe once they are subjected to relaying or depuration. Conditionally restricted means that the water usually meets restricted standards *(i.e.,* shellfish must be relayed or depurated) but predictable pollution events occur that make water unsafe. Areas are classified as prohibited either because there is no current sanitary survey or because any of the dangerous substances listed under approved are present in excessive concentrations. If water is classified as prohibited, the taking of shellfish for any human food purposes from such areas is forbidden.[77]

In order to classify growing areas within one of the five categories listed above, the NSSP Manual sets forth microbiological standards– or the level of fecal coliform bacteria– permitted in the water. In 1986, the NSSP manual was revised for the first time in over 20 years, and the revision lowered the level of fecal coliform indicators permissible in determining the sanitary

NSSP Manual 1995 at C-8

Id. at C-16.

Id. at C-21.

quality of water.[78] The 1995 NSSP Manual states that in order for a growing area to be

approved[79]

[t]he bacteriological quality of every sampling station in those portions of the area exposed to fecal contamination shall meet one of the following standards:

i. The total coliform median or geometric mean MPN [most probable numberf' of the water does not exceed 70 per 100 ml and not more than 10 percent of the samples exceed an MPN of 230 per 100 ml for a 5-tube decimal dilution test (or an MIPN of 330 per 100 ml for a 3-tube decimal dilution test)...

ii. The fecal coliform median or geometric mean MPN of the water does not exceed 14 per 100 ml and not more than 10 percent of the samples exceed an MPN of 43 per 100 ml for a 5-tube decimal dilution test (or an MPN of 49 per 100 ml for a 3-tube decimal dilution test).[8]'

Water samples must be taken from stations located adjacent to actual or potential sources of pollution, and must be collected during times of adverse pollution conditions.[8] This NSSP test has been dubbed the 70-standard. Studies reveal that water with a coliform level of 70 is unlikely to cause diseases related to fecal contamination. An MPN of 70 is equivalent to fecal material contributed from one person diluted in about 2.27 x i0∼ liters (8 million cubic feet) of coliform free water.[83] The NSSP predicts that such a small amount of sewage is of negligible health significance and has probably also been treated, diluted, and aged. In addition to the

Weighing the Risks, supra note 30, at 23.

The 1995 NSSP Manual provides two methods of testing water quality: the adverse pollution condition strategy and the systematic random sampling strategy This paper discusses the adverse pollution condition strategy. The state may use the second testing method, systematic random sampling, only if the water is not impacted by point source pollution. The systematic random sampling strategy was created by the ISSC in 1989. It requires that the total coliform median MPN does not exceed 70 and the 90th percentile does not exceed an MPN of 230 per 100 ml

s The MPN is defined as a statistical estimate of the number of bacteria per unit volume [that] is determined from the number of positive results in a series of fermentation tubes. NSSP Manual 1995 at DEF-2

NSSP Manual 1995 at C-8 to C-9.

NSSP Manual 1995 at C-9.

NSSP Manual 1995 at C-b.

70-standard there is a second part to the NSSP test: the limitation that the upper 10% of contamination not exceed MPN 230. In other words, water that is grossly contaminated 10% of the time may be classified as approved. One author argues that the 70-standard is actually a misnomer: an approved station may have 40% of its sample values in the range of 70-230 and 10% of its samples exceeding 230. Therefore, approximately 1/2 of the samples taken from a routine sampling station... can exceed a coliform MIPN of 70.984

In order to have a complete sanitary survey, agencies must consider not only the microbiological assessment of water but also pollution sources, meteorological factors and hydrographic factors. Direct discharges into water (from septic tanks, or municipal and industrial waste discharges) non-point sources (such as stormwater runoff and wildlife area runoff), tidal amplitude, prevailing winds, water circulation and rainfall patterns will all affect the quality of water and will determine where classification boundaries begin and end. These factors may also determine whether water can be conditionally approved. For instance, a state may condition approval on the wastewater treatment plant achieving a particular level of performance; however. extremely low tides may make the usually sufficient level of treatment inadequate)'[5]

The practice of testing shellfish safety by the presence of indicator organisms is not always accurate. The ratio between the number of indicator organisms and the actual number of pathogens can change with every milliliter of effluent, depending upon such factors as number of carriers or active cases in the population, degree of treatment of sewage, dilution, and other factors.[8~' In other words, just because the level of fecal material is low, one cannot assume that the number of viable pathogens in the water is low. If the water is directly contaminated with

Hunt, *supra* note 67, at 143
NSSP Manual 1995 at C-14
Hunt, *supra* note 67. at 144

small amounts of fresh sewage, bacteriological examination would not reveal a problem– the water would still pass the 70-standard– but human illness may occur. Conversely, shellfish harvested from waters containing relatively high levels of viable sewage organisms could be safely consumed if no pathogens were present.[87] Banning all shellfish from polluted waters is thus both over- and under-inclusive. There are viruses such as Vibrio vulnificus that occur naturally in all water– even unpolluted water. At the other end of the spectrum, acres of water are closed under the microbiological standard without proof of a single contaminated shellfish.

Due process challenges to microbiological standards on the basis of over-inclusiveness have been generally unsuccessful. In 1942, clam diggers went to court to protest the closing of Raritan Bay.[88] They claimed that the closure was arbitrary, capricious and unreasonable because the Department of Health had not shown a single contaminated clam taken from the bay. The court rejected the diggers' claim, holding that [t]he presence of polluted waters is sufficient. Authorities should not wait until contamination is real.[89] In 1961, an outbreak of infectious hepatitis closed the bay completely and over 3,000 fisherman were unemployed.∼ A similar court battle occurred in New York in l977.∼' Based on NSSP standards, the Department of Environmental Conservation (DEC) closed approximately 1500 acres of the Great South Bay, making closed waters in the Bay total nearly 3100 acres.[9]: The court found that the coliform test did not violate due process because it was the most accurate testing procedure currently

87 *Id*

De Roche v Osborne, 179 Misc. 589, 37 NYS. 2d 348, (Sup.Ct, Richmond Co 1942) *See also* Hunt, *supra* note 67, at 144.

179 Misc. at 592.37 NYS. 2d at 351.

.1 *Pollution Narrows, supra* note 22, at 12

Villani v. Berle, 91 Misc. 2d 603, 398 N Y.S. 2d 786 (Sup Ct., Suffolk Co. 1977)

91 Misc. 2d at 613, 398 NYS. 2d at 804 By 1986 the number of acres closed in the Great South Bay had grown to 3,870 (1 30/o) and closed waters in New York were more than 25,000 in 1983. Becker, *supra* note 6, at 11.

available and alternatives were either economically unfeasible or scientifically unacceptable. ~ The court explained that the DEC's decision had a rational basis because it followed NSSP

procedures. The court did, however, empathize with the position of the baymen.

it is small consolation to a bayman who earns his livelihood by shellfish harvesting to tell him that more precise criteria may allow the opening of lands now closed to harvesting; in fact this may not be the case, regardless of whatever criteria is used, if the Great South Bay continues to be used as the repository for society's waste products[94]

Regulation by water quality can produce seemingly unfair results because it provides no

connection between the party causing the health problems and the party being regulated Penalties provide little incentive for increased safety because the harvesters– who are greatly affected by water closings– have little control over the quality of the water. Every year, restricted shellfish harvesting areas are increasing In 1980 almost 3 million acres were closed.[9~] The harvesters intuitively fight the microbiological standards, but it is not the standards that prevent the baymen from clamming– it is the encroachment of pollution.

Even if we acknowledge the inaccuracies of the microbiological standard, no better regulatory alternative seems possible. To avoid banning clean shellfish, agencies would have to test each shellfish for bacterial and viral pathogens; however, there is no routine method of detecting most viral pathogens that exist in shellfish– including severe viruses such as hepatitis A. Furthermore, the sheer volume of shellfish would make it impossible to test a statistically significant sample?'~ Agencies could also require that all shellfish be subjected to heat treatment in

91 Misc. 2d at 610, 398 N.Y S. 2d at 802.

Id. at 613-614, 804.

- Miller, *supra* note 24. Whereas oyster production along the gulf coast and eastern seaboard used to flourish at over 100 million pounds per year, in 1982 production was at 54.3 million pounds– and that was a record high! *Id.* As of 1986, 17% of Long Island's bay bottom (200,599 acres out of 1,188,470) was closed, along with most of New York's other clam-bearing waters. *See The Cop on the Boat, supra* note 21, at 3 1.

Hunt, *supra* note 67, at 145.

order to inactivate microbiological pathogens; however, heat treatment would not eliminate toxic chemicals or marine toxins.[97] Still, the FDA recognizes that more accurate detection methods are necessary. Rather than continuing to rely on indicators, the FDA is developing gene probes and i∼ene amplification techniques to detect viruses directly– new scientific methods that are an offshoot of AIDS research. Some FDA laboratories are concentrating on better detection of Vibrio bacteria alone.[38] Although tests such as the polymerase chain reaction assays can sometimes identify the etiology of an outbreak that has occurred, the FDA is anxious to develop new assays that will detect viral pathogens in products before the products are ever distributed to consumers.[99] The FDA coordinates research activities with the National Marine Fisheries Service, an agency within the Department of Commerce, '∼ and it collaborates with the Center of Marine Biology of the University of Maryland. " The FDA has progressed such that shellfish are now monitored for at least 10 pathogens, including Vibrio vulnificus, Vibrio parahaemolyticus, \ibrio Cholerae, Salmonella, Listeria monocytogenes, Campylobacter jejuni, ecoli, and Yersinia enterocolitica.

In addition to pathogens, shellfish may contain poisonous and deleterious substances such as heavy metals, pesticides, petroleum products, polychlorinated biphenyls, and naturally occurring biotoxins.' '∼ There has been much debate whether the FDA should establish tolerances

Id.

Seafood Safety, Hearings Before the Subcomm. on Fisheries and Wildlife Conservation and the Em'ironment of House Comm. on Merchant Marine & Fisheries, 1 02d Cong., 1st Sess. 6-129, 160-187 (1991) (statement of Douglas L. Archer, Acting Director, Office of Seafood & Deputy Director, CFSAN). [hereinafter Douglas L. Archer].

42 Morbidity & Mortality Wkly. Rep. 49, *supra* note 41.

Dr. Michael Friedman, *supra* note 11.

The FDA's Columbus center, in downtown Baltimore, is particularly aimed to work with the University of Maryland. It specializes in marine toxin research. FDAICFSAN, *Guidance Documents for Trace Elements in Shellfish, supra* note 62.

C Vein Modeland. *Fishing for Facts on Fish Safety,* FDA Consumer, Feb. 1989 at 16, 21
22

for these shellfish contaminants. Tolerances are usefi∼l because if a contaminant exceeds the published standard, there is a presumption that the food violates the Federal Food, Drug and Cosmetic (FD&C) Act'∼ even without proof of harm. Standards are not a prerequisite for agency action, but without them, the FDA must bring an individual enforcement action to establish that the contaminant may be injurious to health. The FDA has one binding legal limit for a seafood contaminant: polychlorinated biphenyls, or PCB's.'[05] The FDA has generally declined to establish more national limits for several reasons. First, tolerance levels are particularly difficult to determine for contaminants because unlike other chemicals, contaminants lack a sponsor who would perform research and develop data.'[06] Second, contaminants tend to be regional problems, best dealt with on a local, rather than a national, level.

The FDA has another option besides tolerances: it may publish action levels under 21 C F R. §109 and §509 Action levels are not binding but serve as guidance to states and the FDA in determining whether food is adulterated within the meaning of the FD&C Act. The FDA has action levels for methyl mercury, paralytic shellfish poison, and 13 pesticides. ∼ Other pollutants present in water (such as heavy metals, radioactive wastes and hydrocarbons) apparently do not pose a threat to human health through shellfish consumption, because shellfish lack the fatty tissue necessary to store these contaminants.'∼[8] Nevertheless, the FDA now tests fresh and fresh- frozen clams and oysters for lead, cadmium, arsenic, chromium and nickel. ∼ In 1993 the FDA

∼ NSSP Manual 1995 at APD-1.

" 21 U.S.C. §301.

21 C.F.R. §109.30 (1984). *See* NSSP Manual 1995 at APD-3. *See also* Thomas J. Billy.

supra note 57.

"∼ Thomas J. Billy, *supra* note 57. The FDA does, however, have the necessary numbers for

paralytic shellfish toxin. James Benson, *supra* note 50.

'∼ Thomas J. Billy, *supra* note 57.

's *Pollution Narrows, supra* note 22, at 12.

NSSP Manual 1995 at APD-2. *See also Pollution Narrows, supra* note 22, at 12.

sponsored a chemical contaminant conference to address the viability of tolerance levels for metals∼ but no toxic metal guidelines have been adopted by the NSSP. Instead, FDA has developed guidance documents to be used by the states in assessing the public health impact of metals."'

With any foodborne illness, it is difficult to tabulate the actual outbreaks of infection. Agencies cannot be certain of risks posed by a particular food because foodborne illness is not always recognized or properly diagnosed; and because the system for generating and collecting reports on foodborne illness experiences significant underreporting. Agencies also cannot compare the relative safety of different foods based on foodborne illness data reported to the CDC, because the rate of reporting varies from one food type to the next.[3] The method of determining a source of food poisoning is still simple at best. New York State, for example, requires that any case of food poisoning be reported to health officials. The New York State Health Department then attempts to discover whether an outbreak– two or more illnesses linked to a common source' 'h– has occurred. The Department uses a food specific rate attack table to compare the number of people who become ill after eating a specific food with the number of people who became ill and did not eat that food.[5] Thus, the state relies on a mere process of elimination to reveal the contaminated food source. Ironically, New York State's Department of Health has had the most extensive foodborne disease surveillance program in the nation since

1980.'

Thomas J. Billy, *supra* note 57.

NSSP Manual 1995 at APD-1

Thomas J. Billy, *supra* note 57.

IK∼ *Id*

∼ Miller, *supra* note 24.

New York State Department of Health, *ShelWsh Related Illness, supra* note 23.

∼ COSMA. *supra* note 72, at S.

Recognizing whether or not an outbreak has occurred becomes even more difficult when data must be coordinated between the many different agencies receiving illness reports. The Active Foodborne Disease Surveillance Network has five sentinel sites at state health departments to track foodborne illnesses in order to determine their common sources; however, the FDA has admitted that more sites are needed and that they ought to be electronically linked together in order to identify patterns of illness. In fact, the FDA has declared that in order to prevent the spread of foodborne disease such an early warning system is indispensable.[7] The FDA has also proposed the creation of a Foodborne Outbreak Response Coordinating Group, which would include representatives from both state and federal agencies and would further integrate information.[8]

Until state and federal agencies achieve better coordination and data collection, we will neither know the true incidence of seafood illness, nor be able to prevent the spread of those illnesses. Furthermore, science must develop a more accurate means of discerning the contaminated shellfish in order to stop banning shellfish that are in fact safe for consumption. Until science makes these discoveries, regulations will continue to rely on microbiological standards that produce errors in both directions: they ban safe shellfish, and yet contaminated shellfish continue to reach the consumer.

" Food Safety, *supra* note 12.

s *Id*

Chapter Three

1906-1956: In the Beginning

The 1906 Federal Food and Drugs Act[9] prohibited the manufacture, interstate shipment or export of any article of food or drugs which is adulterated or misbranded. It was the combined responsibility of the Secretary of Treasury, the Secretary of Agriculture and the Secretary of Commerce to make uniform rules and regulations consistent with the act. Since the definition of adulterated included filthy, decomposed or putrid animal or vegetable substance∼ ∼ sea food would conceiveably be regulated under this statute; however, the success of this program came into doubt in 1924 when an eruption of typhoid fever produced 1500 cases of illness, 150 deaths, and was traced to the consumption of oysters that had been harvested from sewage-contaminated waters " The publicity of these illnesses made the public unwilling to purchase oysters. When sales dropped, the shellfish industry appealed to the Public Health Service to develop a program that would restore confidence in their product.'∼ The formation of the NSSP a year later is often attributed to this outbreak of typhoid'[3]; however, the need for greater control over seafood had already become clear during the war when the Food Administration had encouraged the consumption of fresh fish.'[4] It is at least certain that the typhoid outbreak engendered new interest in the monitoring of shellfish.

∼ Pub L No. 59-384, 34 Stat. 768 (1906) as amended.

ld.

Rep No HRD-84-36 (1984). An earlier typhoid outbreak, which had occurred in 1910.

was also traced to polluted water. In 1910, raw sewage from a city of 30,000 was being discharged only a few hundred feet away from clam beds. NSSP 1995 at C-9.

Pollution Narrows, supra note 22.

∼:; Rep No. RCED-88-135 at 10.

'∼ FSA Ann Rep. 535 (1946).

In response to the industry's request, the Surgeon General called a conference of iepresentatives from State and municipal health authorities, State conservation commissions, the Bureau of Chemistry (later to become the Food and Drug Administration), the Bureau of Commercial Fisheries (now the National Marine Fisheries Service) and the shellfish industry This Conference on Shellfish Pollution took place in Washington, D.C. on February 19, 1925. The conference established eight resolutions for the sanitary control of the oyster industry and created a committee to develop further guidelines as needed. The resolutions addressed not only the quality of the beds from which oysters were harvested, but also the packing, shucking, shipping, storing, and displaying of oysters. '∼

Many of the conference's concerns were then incorporated into the National Shellfish Sanitation Program (NSSP), which was implemented that same year. The NSSP is a voluntary, cooperative program that addresses the sanitary control of fresh and fresh frozen molluscan shellfish (oysters, clams, and mussels) offered for sale in interstate commerce.[27] The NSSP excluded crabs, scallops and shrimp from regulation on the theory that they are not vulnerable to contamination through the pollution of their beds in the same way as oysters, clams and mussels.'[8] The policies of the NSSP mark a very important change in the way regulators were thinking about shellfish regulation. Formerly, state agencies were forced to monitor shellfish after harvesting, when contamination had for the most part already occurred[9]; the NSSP. however. forbade contaminated shellfish from being harvested. The NSSP banned harvesting from polluted waters by setting forth three water quality criteria: first, water must be sufficiently removed from

NSSP Manual 1995 at ix.

' 40 Fed. Reg. 25916, 25917 (1975).

:' 49 Fed. Reg. 31774, 31775 (1984).

Pollution Narrows, supra note 22, at 10.

Id

major sources of pollution so that shellfish are not exposed to fecal contamination in a quantity dangerous to health; second, the area must be free from even small quantities of fresh sewage; and third, bacteriological examination may not ordinarily show coli-aerogenes bacteria in I cc dilution of water.

In a letter dated August 25, 1925, the Surgeon General described the NSSP in terms of a relationship between the states and the Public Health Service (PHS). ' Attributing the actual regulation of shellfish to the individual state, the Surgeon General explained that the PHS, aided by the 1925 Conference Committee, merely acts to coordinate the regulation. The PHS' particular role was to survey the states and publish reports on the effectiveness of the state control programs. This fact gathering was first compiled in a Report of Committee on Sanitary Control of Shellfish Industry in the United States on November 6, 1925, as a supplement to the Public Health Reports. Later, this report would be replaced by a program endorsement concept, under which the PHS evaluated each state's compliance with the Manual of Recommended Practice for Sanitary Control of the Shellfish Industry.'[3] The NSSP also published a list of all shellfish shippers certified by those States having 'satisfactory' control programs.'[33]

The NSSP continues today as a tripartite cooperative program, made up of shellfish-producing states, the FDA, and the shellfish industry. Seven foreign countries also participate through agreements signed with the PHS and the FDA.'~ The FDA administers the NSSP, but

NSSP Manual 1995 at C-4.

49 Fed Reg 31774, 31775 (1984).

The program endorsement concept arose in 1946 with Public Health Bulletin No. 295.

Intervening was the 'L'S. Public Health Service Minimum Requirement for Approval of States Shellfish Control Measures and Certification for Shippers in Interstate Commerce (Revised October 1937).

'~ 40 Fed. Reg. 25916, 25917 (1975). *See also* Supplement No. 53 to Public Health Reports, November 6, 1925 Report of Committee on Sanitary Control of Shellfish Industry in the United States.

the states must create laws providing themselves with adequate legal basis for the sanitary control of all interstate phases of the shellfish industry.'[35] Each NSSP member has particular responsibilities: the states identify pollution, test water for bacteriological quality, patrol growing areas, certify shellfish plants, conduct laboratory experiments and ensure that shellfish are harvested and processed under sanitary conditions; the FDA reviews state programs (in order to evaluate conformity with NSSP) and suggests improvement; and the industry agrees to harvest and produce under sanitary conditions, including the use of tags and records to monitor the origin and disposition of shellfish.'[36] The NSSP publication today is called the National Shellfish Sanitation Program Manual of Operations. This two-volume manual provides guidance to states in creating shellfish laws and regulations. The FDA also uses the NSSP Manual as a basis to certify foreign shellfish sanitation programs. ~ The manual addresses general administrative procedures, laboratory procedures, and guidelines for growing area survey and classification, controlled relaying, patrol of shellfish harvesting areas and control of harvesting, and acquaculture.'[38] Thus, the creation of the NSSP in 1925 set the stage for what may be today the most important regulatory vehicle in the history of shellfish.

On June 22, 1934, the 1906 Federal Food and Drugs Act was amended by adding Section I OA, applying to seafood. '~ This amendment was probably in response to difficulties with

50 Fed. Reg. 7797 (1985); 54 Fed.Reg. 7281 (1989).

'~ NSSP Manual 1995 at A-I.

'~ 4OFed Reg.25916(1975).

'~' NSSP Manual 1995 at xv.

138 Introduction to online NSSP Manual of Operation, FDAICFSAN 1995, *available at*
http://vm.cfsan.fda. govb—ear/nsspman html In 1982 the Interstate Shellfish Sanitation
conference was established. Today, the NSSP Manual is updated at the ISSC's annual conference.
with input from the State Shellfish Authority, shellfish industry, and federal regulatory agencies
such as FDA, NMFS and EPA

'~ Pub.L No. 451, 48 Stat 1204.

decomposition of shrimp in the Gulf of Mexico Area.'~ The new section gave the Secretary of Agriculture discretion to examine and inspect all premises, equipment, methods, materials, containers and labels used in the production of seafood upon application by the packer of seafood. The applicant had to pay a fee, and upon passing inspection, was authorized to mark the seafood as conforming to federal regulations. This section was amended only a year later, on August 27, 1935.'~' The basic provision remained the same, but the amendment potentially expanded the application of the statute because it empowered the Secretary to inspect any seafood within the jurisdiction of this act, rather than limiting inspection to only the sea food sold in interstate commerce. The 1935 amendment also may require the applicant to affix the mark, and may charge fees not only to cover expenses but also to provide, equip and maintain an adequate and efficient inspection service. Furthermore, the Secretary can use the receipts from these fees toward salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. Finally, the amendment authorized the Secretary to promulgate regulations establishing the sanitary and other conditions under which the service herein shall be granted and maintained.

When the 1906 Federal Food and Drug Act was replaced by the Federal Food, Drug, and Cosmetic Act of 1938,'~ Section bA.. was the only provision not repealed.'[43] Rather, Section IOA was amended to become §702A (21 U.S.C. §372A),'~ later to be renumbered as §706 (21 U.S.C. §376).'~~ Section 706. which is still in effect today, is basically identical to

55 Fed. Reg. 26334. 26337 (1990).

Pub. L. No. 346,49 Stat. 871.

~ 21 U.S.C. §301.

'~ Peter Barton Hutt & Richard Merrill, Food & Drug Law, 267 (1991).

'~' PubL No. 102-571, 106 Stat. 4498 (1992)

'~ Pub. L No. 103-80, §3(dd)(2), 107 Stat. 779 (1993).

Section 1 OA as promulgated in 1935. The earlier version had authorized inspections by the Secretary of Agriculture, because in 1935 the FDA was a part of the U.S Department of Agriculture. The amendment to Section 706 deleted the words of Agriculture because by that time the FDA had become part of the Department of Health and Human Services (HI-IS). More importantly, the survival of Section 1 QA means that the FDA has had continuous power to inspect shellfish since the first act in 1906.

With the enactment of the Public Health Service (PHS) Act in I944,'~ the FDA acquired further regulatory power The PHS Act authorizes regulations that prevent the spread of communicable diseases. The FDA also has some power to protect against insanitary food conditions at the retail level. The 1906 Act forbade any person to sell or offer for sale adulterated foods received from interstate shipment, ~ and Section 331(k) of the 1938 Act prohibits any act if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded The FDA has not in fact established regulations for restaurants, food vendors or retail food stores: instead, the FDA develops model codes and ordinances to be enforced by state and local agencies. The use of model legislation began with the PHS, when it prepared a Food Service Sanitation Ordinance in 193 5~48 In 1957, the PHS added a Vending of Food and Beverages Ordinance, and later the FDA contributed its own Retail Food Store Sanitation Code.'[49] Although the FDA once considered converting these model ordinances into regulations, lack of enforcement resources and general opposition convinced the agency to leave regulation of

~ 42 U.S.C. §201. 58 Stat. 682; Regulations to Control Communicable Diseases 42 U S.C §264, 58 Stat. 703.

§2, Pub. L. No. 59-384, 34 Stat. 768 (1906), as amended.

~ Hutt, *supra* note 143, at 268.

'~ *Id.*

the retail sector to the states.'∼[0] Nevertheless, the combination of the FD&C Act and the PHS Act has paved the way for the FDA to become a strong force in the control of seafood safety.'[5]'

Not long after the FDA acquired additional regulatory authority under the PHS Act, the National Marine Fisheries Service (NMIFS) of the Department of Commerce also acquired a role in shellfish safety. The NMIFS is charged with conserving, managing, developing and protecting living marine resources that depend upon healthy and productive marine and estuarine habitats Under the Agriculture Marketing Act of 1946's the NTvIFS operates a voluntary fee-for-service inspection program.'∼ Regulations are codified in 50 C.F.R. §§260-266, which develop names and standards for grades of fish. In the Fish and Wildlife Act of l9561∼ the Director of the Budget transferred all duties pertaining to fish, shellfish and any products thereof to the Department of the Interior. This transfer actually encompassed those duties performed by the Department of Agriculture under the Agriculture Marketing Act of 1946.156 Nonetheless, the NMIFS continued to operate its voluntary program that includes inspection, grading, and certification. as well as the use of official marks to indicate whether a product has been federally inspected. In 1990, the NMFS program covered about twelve percent of seafood consumed in this country, and nine percent of edible fishery exports.

Id. The FDA later combined all of the model ordinances and codes into a single Food Protection Unicode.

55 FedReg. 26334 (1990)

Rep No. RCED-88-135.

Pub L No. 733, 60 Stat. 1082, as amended in 7 U.S.C § 1622

Hutt, *supra* note 143, at 1332.

Pub L No. 1024, 70 Stat. 1119 (16 U.S.C. §742(e)).

Later, Reorganization Plan No. 4 of 1970 (84 Stat. 2090) transferred these functions back

to the Department of Commerce.

'∼ 55 Fed. Reg. 26334 (1990) In 1983, NIvffS covered 18% of seafood consumed and I

in 1987. Hutt, *supra* note 143, at 268.

From the NMFS program onward, the subject of shellfish produced much scientific discussion. The PHS created the Public Health Service Shellfish Sanitation Laboratory in 1948, in order to provide a forum for conducting bacteriological studies on the problems of shellfish sanitation. In 1955, an annual publication called The National Shellfish Proceedings focused much attention on the laboratory's latest discoveries. That year, the Shellfish Proceedings printed a Convention Symposium on Pollution Control in Shellfish Growing Areas. The symposium was arranged by Acting Chief of the PHS Shellfish Sanitation Section, Eugene T. Jensen.'[58] One study revealed a correlation between the presence of indicator organisms and pathogens. Another discovered that Salmonella could survive in shellfish from harvest until the time of consumption. Because soft clams could not survive transplantation from polluted to clean harvesting beds, the laboratory had sought an alternate method of cleaning polluted clams; the result was artificial purification, which entailed immersing shellfish in clean water. '~ The 1953 study believed that its new purification method could reduce Salmonella to indeterminate levels within 48 hours. A more sobering conclusion was that shellfish are vectors of enteric disease organisms and have the ability quickly to reflect the sanitary condition of their acquatic environment.'[6]'~ In 1953, the PHS Shellfish Sanitation Laboratory was transferred from Wood's Hole. Massachusetts to Pensacola, Florida so that further studies could be performed in a warmer environment. The PHS created a Shellfish Advisory Panel to help develop a research program for the new laboratory.

One year later, in 1954, the First National Shellfish Sanitation Workshop was held in Washington, D.C. It is this workshop that supported dividing the NSSP Manual into the two

C B Kelly, *Public Health Service Research on Shel~fish Bacteriology,* National Shellfish

Proceedings, 1955, at 21.

'~ This depuration method is still used today.

'~ C.B. Kelly, *supra* note 158, at 25.

volumes that appeared in 1957 and 1959. For many years the FDA continued to sponsor National Shellfish Sanitation Workshops as an invaluable resource for revisions to the NSSP Manual.'[6]' Thus, the years between 1906 and 1956 present a recurring theme: the problems with shellfish required more investigation– and more structured supervision. The FD&C Act and the PHS Act formally delegated power to the FDA, but the Workshops, the NSSP and the NMFS played equally important roles in identifying obstacles to shellfish safety. Finally, by turning the attention of the scientific field to shellfish sanitation, the government prompted discoveries crucial to the regulatory measures in place today. A survey of the first fifty years of shellfish regulation reveals the very building blocks that shaped regulations for the next fifty years.

NSSP Manual 1995 at xii. Additional workshops have taken place in 1956, 1958,1961 1964, 1968, 1971, 1974, 1975 and 1977. Idat xiii.

Chapter Four

1956-1980: Shifting Sands

The years from 1956 to 1980 form a roller-coaster ride of decreasing and increasing shellfish regulation. Under then-Section 702A, for example, the FDA had added regulations for the inspection of canned oysters in 1944.6: In 1957, however, only two canneries operated under Section 702A'[63] and at the end of the year the entire voluntary inspection service was discontinued. '~ In contrast, less than a decade later another regulation set forth the specifics of inspecting and certifying fishery products, codified at 50 C.F.R. §260.~6S While the administrative agencies were vacillating on the issue of inspections, the legislative branch was also toying with the idea of regulation. Several Congressional hearings evaluated proposals to establish a continuous factory inspection program for fish similar to those established for meat, poultry and eggs.'[66] Proposals included the Fishery Products Protection Act of 1967 and the Wholesome Fish & Fishery Products Act of 1969.'~~

Between 1957 and 1962 the PHS distributed four publications containing recommended practices for sanitary control of shellfish.'[08] The PHS also created a manual on the Appraisal of

21 C.F.R. §85 et seq. (1944). *See* 55 Fed. Reg. 26334, 26337 (1990). When the voluntary inspection program was re-enacted in 1977, it was redesignated as 21 C.F.R. § 197. '~'~ Hutt, *supra* note 143, at 268.
22 FedReg 891,22 Fed. Reg. 3841 *(1957). See a/so 55* Fed Reg. 26334, 26337 (1990).

Inspection and Certification of Establishments and Fishery Products for Human Consumption, 31 Fed. Reg 16052 (Dec. *15,* 1966) as amended 36 Fed. Reg. 21037 (Nov. 3, 1971), codified at 50 C.F.R. §260.

'~'~ Hutt *supra* note 143, at 268. '~ Rep No. RCED-88-135.

1957 Manual of Recommended Practice for Sanitary Control of the Shellfish Industry (Part II: Sanitation of the Harvesting and Processing of Shellfish). Printed as Part II of Public Health Service Publication No. 33.

1959 Manual of recommended Practice for Sanitary Control of the Shellfish Industry

State Shellfish Sanitation Programs.'∼[9] The Shellfish Sanitation Workshops of 1961 and 1964 reviewed and revised this draft manual, and published a two-volume NSSP Manual in 1965 that greatly resembles the NSSP Manual used today.'[70] In determining final revisions, the FDA relied not only on previous manuals but also on Environmental Protection Agency (EPA) rules and regulations dealing with water pollution and shellfish waters. By incorporating EPA rules, the FDA produced a manual that places great emphasis on water quality and preharvest sanitation. The voluntary procedures stipulated in the manual are still currently used by the Food and Drug Administration in meeting its agreed-upon responsibilities under NSSP

The decade's biggest step in the direction of shellfish regulation was the Reorganization Orders of 1968. In the Reorganization Orders the Department of Health, Education and Welfare'[73] designated the FDA as the principle federal agency responsible for shellfish regulation, thereby transferring regulatory power from the PHS to the FDA.'[7]' Since 1968, the FDA has cooperated with the NSSP and has followed its Manual of Operations, but some have contended that the 1968 change of power produced a change in philosophy, moving from the more cooperative relationship established by the PHS, to an enforcement-oriented program run by the

(Part I: Sanitation of Shellfish Growing Areas) Printed as Part I of Public Health Service Publication No. 33.

1962: Cooperative Program for the Certification of Interstate Shellfish Shippers, Part II, Sanitation of the Harvesting and Processing of Shellfish. (Printed as Part II of Public Health Service Publication No. 33)

1962 Cooperative Program for the Certification of Interstate Shellfish Shippers, Part I, Sanitation of Shellfish Growing Areas. (Printed as Part I of Public Health Service Publication No.

33).

'∼' 40 FedReg. 25916, 25918 *(1975).*

National Shellfish Sanitation Program Manual of Operations Part I, Sanitation of Shellfish Growing Areas, Public Health Service Publication No. 33.. Revised 1965.

NSSP Manual 1995 at xiv. These EPA regulations appear at 40 C.F.R. §§400 et seq. m 40 Fed Reg. 25916. 25919 (1975).

NSSP Manual 1995 at xiii.

'∼ 33 Fed.Reg. 9909 (1968) (codified in 21 C.F.R. §2.120).

FD.-\ Indeed, the FDA has authority under the FD&C Act to make and enforce regulations regarding the sanitation of shellfish that enter interstate commerce.'[76] Generally, however, the FDA has relied upon the NSSP and its policymaking process to ensure shellfish safety.[177] Both the FD&C Act and the PHS Act permit the FDA to accept assistance from the states,'[78] but some criticize this federal-state interaction as an uneasy relationship. The NSSP seeks state compliance through the monthly publication of the Interstate Certified Shellfish Shippers List (ICSSL), which catalogues whether a state's safety program is endorsed. Withdrawal of endorsement penalizes a state, because any state who participates in the NSSP will not accept uncertified shellfish However, under its voluntary agreement with the NSSP, the FDA lacks unilateral power to remove an individual shipper from the endorsement list. Because of its reliance on the NSSP, the FDA has not been inspecting shellfish firms for violations of the Federal Food, Drug & Cosmetic Act, nor has it initiated any Federal regulatory actions against State certified shellfish shippers. To make matters worse, the FDA cannot control the growing area from which shellfish are harvested because its authority is limited to products in interstate shipment.'[5~' Nevertheless, the Reorganization Orders of 1968 marked an enormous step in centralizing the responsibility for shellfish safety.

The year 1970 brings this fifteen year time period back full circle with the Reorganization Plan No. 4 of 1970,'~' which transferred the regulatory power held by the Department of the Interior under the Fish and Wildlife Act of 1956 back to the Department of Commerce. The same

Rep No HRD-84-36 at 43.

21 U S.C. §301.

~ 40 Fed Reg. 25916, 25919 (1975).

'~ 21 U.S.C. §372, 52 Stat. 1056 (1938); 42 U.S.C. §243, 58 Stat. 693 (1944).

17Q 40 Fed. Reg. 25916, 25919 (1975). Rep No. HRD-84-36 at 3.

84 Stat. 2090

Reorganization plan also established the National Oceanic and Atmospheric Administration (NOAA) under the Department of Commerce. The NOAA plays a role in seafood safety because some of its duties include mapping coastal and estuarine waters and managing and conserving fishery resources in conjunction with the states. The NOAA has the authority to close Federal waters to fishing whenever oil spills, toxic blooms or other phenomena threaten to impact the safety of the ∼ The NO∼ uses FDA safety standards when operating its voluntary fee-for- service inspection program for seafood processors. Furthermore, three of the NOAA's components– the NMFS, the National Ocean Service and the Office of Oceanic and Atmospheric Research– have particular programs affecting seafood safety. '∼ The Reorganization Plan of 1970 also added §260.1 to the already-existing inspection program at 50 C.F.R. §260. Section 260.1 grants to the Secretary of Commerce the power to administer regulations regarding inspection and certification of fishery products, except as he delegates such functions to the NMFS '∼'

The uneasy federal-state relationship created by the NSSP finally erupted in a court battle in 1972. The state of Virginia challenged the authority of the FDA and the NSSP to enforce certification of state control programs. Unhappy with an unsatisfactory shellfish program rating, the state questioned the FDA's authority to impose FD&C Act sanctions on a state who shipped shellfish after its program had been decertified by the NSSP. Since the NSSP is voluntary, the probability of a court upholding sanctions seemed unlikely, and the Department of HI-IS' Office of General Counsel wrote a memorandum inquiring as to the legal status of the NSSP. The battle resulted in FDA's conclusion that it had no authority to decertify a state since the NSSP had never been formerly [sic] adopted under the Federal Administrative Process Act.' '∼'

is: Dr Michael Friedman, *supra* note 11.

'∼' Rep No. RCED- 88-135.

'∼ 36Fed. Reg 21037(1971). codifiedin 50C.F.R§260.1.

Despite Virginia's challenge to the FDA, the general cry for formal regulation of shellfish seemed to be growing in volume. The General Accounting Office (GAO) published a study in 1973 that found severe problems with the system of shellfish regulation.'[86] Shellfish that failed to meet NSSP standards continued to reach the consumer market, the states neither ensured the harvesting of shellfish from sanitary waters nor prevented illegal harvesting, and violative shellfish were almost never traced to their source. The GAO's horror stories provided an excellent basis for the Commissioner to suggest the need for formal regulation; thus, on January 14, 1975, the Commissioner announced the prepublication draft, open for comment, of a proposal to strengthen the NSSP.'[87]

In the meantime, two events occurred: first, the FDA and the NMFS executed a memorandum of understanding (MOU);'[88] and second, 21 C.F.R. §1240.60 codified the prohibition against interstate transport of any shellfish that might contribute to communicable disease.'[69] Under the MOU between the NMFS and the FDA, NMFS inspections will ensure that an industry participant complies not only with NMIFS' own requirements but also with the requirements of the FD&C Act. The 21 C F.R. § 1240 regulation prohibited transport of shellfish handled or stored in such an insanitary manner, or grown in an area so contaminated as to render the shellfish a likely agent in spreading disease. The codification of this ban was particularly significant because it was the first episode of shellfish regulation promulgated in the

~ Rep No HIRD-84-36 at 43.

'~' GAO, Protecting the Consumer from Potentially Harmful Shellfish (Clams, Mussels, and Oysters) Rep. No. B-164031(2) (March 29, 1973).

'~ 4OFed.Reg. 25916, 25921 (1975).

40 Fed. Reg. 3025 (1975).

'~ 40 FedReg. 25916, 25918 (1975), codified in 21 C.F.R §1240.60.

federal register instead of relying on the cooperative- voluntary efforts of State regulatory agencies and the shellfish industry.'∼

Perhaps elated by the success of2l C.F.R. § 1240, the FDA published proposed regulations for mandatory control of shellfish the following summer.'[9]' The June 19, 1975 regulations left primary enforcement of shellfish safety requirements to the states; however, they also endorsed the power of the FDA to enforce compliance under the FD&C and PHS Acts, and they specifically permitted the FDA to prosecute individual firms who failed to comply with good manufacturing practices. The FDA retained its former authority to withdraw endorsement of a state program, but the proposed regulations would obviate the need to use withdrawal as anything other than a last resort. The proposed regulations addressed the earlier concerns about tracing violative shellfish by increasing the tagging requirements. The proposition also incorporated comments that had been made in response to the earlier draft; for example, since other regulations were being developed to provide federally enforceable controls on the marketing of perishable food, the revision deleted its own requirements for shellfish market control

Apparently because of considerable confUsion about the intent and interpretation of the proposed regulations, the Commissioner later announced that he would revise the June regulations and reissue them for comment,'[9] but he never succeeded in reissuing these regulations. A 1984 GAO report summarized the episode as an attempt to formalize proposed regulations that was withdrawn because of opposition, '∼ but the abandonment of the regulations can also be specifically attributed to antipathy of Congress.'∼[4] In the Bauman Amendments to the

∼' *Id*

Id at 25921.

∼ 40 Fed. Reg. 58883 (1975).

'∼ Rep. No HIRD-84-36

'∼ *See, e.g.,* Hutt, *supra* note 143, at 1317: [B]efore it could be revised by the FDA

Coastal Zone Management Act of l976,'∼∼ Congress prohibited the Secretary of Health, Education, and Welfare (and, therefore, the FDA) from promulgating final regulations concerning the national shellfish safety program before June 30, 1977.'∼ Furthermore, if the FDA were to create such regulations, it first had to conduct an economic analysis of the regulations' impact on the shellfish industry and a cost-benefit analysis of the proposed NSSP. Finally, and somewhat ironically, this period of upheaval closed with a regulation that merely continued the former procedures for inspection of canned oysters: the voluntary inspection program that had been discontinued in 1957 was revised and redesignated as 21 C.F R. §l97.'∼'

Congress acted to postpone the proposal; Peter Barton Hutt, *199S- An Overview of the Last 50 Years,* 50 Food & Drug L.J. 197 (1995) In 1977 Congress passed the first of several laws precluding FDA from controlling shellfish.

Pub L No. 94-370, §16 B, 90 Stat.1013.

Id at 1033.

C7 42 Fed. Reg 14303, 42 Fed Reg 14661 (1977). In 1996, the cannery inspection under 21 C.F.R. §197 was again discontinued. 61 Fed. Reg. 27779 (1996).

Chapter Five

The Eighties and The Outbreaks

The Commissioner's failed attempt to establish formal regulations in no way diminished general interest in the monitoring of seafood safety. In its report Need to Assess Quality of V S -Produced Seafood for Domestic and Foreign Consumption, the GAO concluded that the variable quality of U.S. seafoods contributed to the low volume of seafood consumed domestically and exported.'[98] The report recommended that the Administrator of the NOAA perform a study to assess the quality of U.S. seafood. When it appeared that the project would not be funded, the GAO issued a second report, Followup on the National Marine Fisheries Service's Efforts to Assess the Quality of U.S-Produced Seafood.'~ The second report reiterated the importance of conducting a study on seafood. It also suggested that the industry and the NT'VIIF S formulate a grading system for fish quality and establish price differentials as a means of rewarding fishermen for high quality fish.

A triumph in the regulation of shellfish occurred with the Lacey Act Amendments of 1981, ~ which permit any federal agency to enforce the prohibition against buying, selling or transporting any fish, wildlife or plants possessed or taken in violation of any law, treaty or regulation. Although this amendment authorized the FDA to initiate enforcement action, it is actually the NMFS who is now responsible for the control of illegally taken molluscan shellfish. due to an MOU created between the NMFS and the FDA in 1986.:~~ Still, the most successful operations have involved the NMFS and FDA working together to prove Lacey Act violations

'~ Rep. No. CED-81-20 (Oct 15, 1980).
Rep No CED-81-125 (Jun. 22 1981)
16 USC. §3371 (1981).

v

In 1987, the NMFS and FDA formed a joint operation against illegal harvesting that had become rampant in Louisiana, Florida and South Carolina.~ One FDA investigator estimated that 20% of shellfish leaving Louisiana were harvested from polluted waters, and one South Carolina dealer allegedly sold more than one million dollars worth of illegally obtained clams in a vear!'[3] Because there are three and a half million acres of shellfish growing waters in Louisiana alone, the state's small patrol force was unable to solve the bootlegging The FDA and NMIFS thus launched a full scale undercover operation: federal agents were joined by the Florida Department of Natural Resources, Florida Marine Patrol, Louisiana State Police, South Carolina Wildlife and Marine Resources Division, and the South Carolina Department of Health and Environmental Control. The U.S. Coast Guard provided air flights over the illegal waters to track the harvesters. Federal agents posed as fisherman and attempted to sell untagged oysters to the dealers who were suspected of trading in illegal harvests. During the sale, the undercover agents indicated that the oysters had come from illegal waters, providing the FDA with documentation that dealers purchased sacks of untagged oysters and sacks of oysters believed to be from closed waters. Each violation of the Lacey Act carries a $20,000 fine, up to five years in jail and parallel state law violations. Y)-1 The federal agencies targeted the dealers in the hope that by destroying the market for illegally harvested shellfish they would discourage fisherman from illegal harvesting.

The 1981 triumph of the Lacey Act was followed by another step forward in shellfish regulation with the formation of the Interstate Shellfish Sanitation Conference (ISSC) on Sept 21,

Rep. No RCED-88-135.

Dale Blumenthal, *Catching Fish in All the Wrong Places,* FDA Consumer, Feb. 1989 at 22. The operation was so large that it involved three separate undercover investigations, code-named PEARL in Louisiana, STOP in Florida, and SPONGE in South Carolina. *Id.* at 23.

Id.

16 U.S.C. §3371 (1981).

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1982 The participants of the ISSC include regulatory officials from twenty-two states, the FDA, the NMFS and members of the shellfish industry. The purpose of the voluntary program is to provide a medium through which state regulatory officials can establish updated guidelines and procedures for the uniform application of those guidelines for sanitary control of the shellfish industry.[05] The first annual meeting was held in August 1983, at which the ISSC adopted the NSSP Manual and various administrative procedures necessary to modify the manual On March 30, 1984 the 1-Il-IS published notice of an agreement between the FDA and the ISSC. The agreement essentially affirms the continued exchange of information between the agencies regarding state compliance with shellfish sanitation programs. The FDA consents to evaluate shellfish sanitary control programs and report its findings to the ISSC7'[6] publish revisions to the NSSP Manual of Operation'[07] and provide technical assistance to the 155C[08] The promised revisions to the Manual of Operation have taken place nearly every year since 19867's

The 1980's contain further evidence of the increased interest in seafood safety. In 1982, the Seafood Technology Division was established within the Institute of Food Technologists (IFT))' lET is, in turn, a nonprofit scientific society devoted to the discovery and application of knowledge to improve the world's food supply. The Seafood Division takes advantage of the forum already established by IFT in order to bring attention to seafood issues. By 1996 the Seafood Division had acquired more than 625 members from academia, industry and government.

49 Fed. Reg. 12751, 12752 (1984).

- *Id.*

:r∼, 49Fed. Reg. 31774, 31775 (1984).

54 Fed Reo 7∼'8l (1989'i

∼ NSSP Manual 1995 at iii. Revisions occurred each year from 1986 to 1990, then again in

1992, 1993 and 1995. *Id.*

Seafood Network Information Center, Institute of Food Technologists, *Seafood Technology Division,* UC Davis, *available at.* http: //ift.mcrine∼.com/ divisions! seafood! member. htm?L+mystore-'44

2

The Seafood Division's objectives include: encouraging cooperation between IFT members in industry, government and academia who work with seafood products; fostering symposia regarding seafood science and technology; and stimulating and assisting pertinent research and development in seafood technology.

Several illness outbreaks occurred between 1982 and 1983, and many responded by demanding federal involvement. In 1982 at least 471 persons became ill after consumption of sewage-contaminated oysters. It was discovered that the combination of raw sewage bypasses, high rainfall, strong winds, and low tides caused contamination of water that was classified as approved under NSSP standards.:[11] The NSSP Manual suggests that, had the water been classified as conditionally approved, the required monitoring would have prevented the outbreak. Additionally, a survey of the quality of shellfish tagging in New York retail establishments at that time revealed that 14% of the establishments were selling improperly tagged or untagged clams[7] In December 1982, over 250 more illnesses associated with clams and oysters occurred. Because the outbreak was severe in Long Island, the New York State Department of Health (DOH) issued three advisories warning against the consumption of raw clams and oysters)'[3] The DOH also proposed to embargo shipments from any state whose clams were verified as causing illness. The consumer public, formerly slow to react, began to avoid purchasing clams. Nevertheless, local Baymen maintained that clams were not responsible for the illnesses; the Baymen blamed other foods, the flu, and the DOH for making accusations it could not prove)'[4] Finally, in early 1983 a meeting between the FDA, six shellfish-interested states, the CDC and the ISSC convened in

NSSP 1995 at C-14.

Becker, *supra* note 6, at 21-22.

Id.

∼ *Id* at 24.

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Albany, NY to discuss a regional solution to the shellfish problem. The group rejected the DOH's proposed embargo, instead deciding that interstate sanitary control required greater federal participation.

This cycle– proposal by the state, rejection by the industry and request for federal help–repeated itself when the New York DOH suggested banning the sale of raw shellfish. Such a ban would devastate the New York shellfish industry, where an estimated 70 to 80% of hard clams are sold to restaurants and 70 to 80% of those clams are eaten raw)'S At the request of several Baymen's groups and the Suffolk County Hard Clam Advisory Group, a workshop was convened to develop alternatives to the DOH's ban. The workshop observed that most outbreaks were attributed to illegally harvested shellfish, but until diggers were convinced of the real threat to human health, poaching would not be eliminated, One recommendation was to adopt national strategies and standards for the harvest, distribution and marketing of shellfish.

In 1983, after 750 New Yorkers became ill from eating raw clams, Congressman Thomas J. Downey requested that the GAO examine the FDA's role in regulating the interstate shellfish industry. On June 14, 1984, the GAO published Problems in Protecting Consumers from Illegally Harvested Shellfish (Clams, Mussels, and Oysters). ∼:∼6 The report concluded that although the FDA reviews state programs and suggests improvements, it has no enforcement authority to ensure adherence to program guidelines. The report went on to identify three basic weaknesses in the current system: shortage of enforcement staff little deterrent effect of penalties; and inability to trace contaminated shellfish ∼ The situation in New York confirms the GAO's

:1s COSMA, *supra* note 72, at 6.

∼ Rep. No HRD-84-36 (1984).

: ∼ The GAO was not alone in identifying these weaknesses. *See also* COSMA, *supra* note 72 at 12; Becker, *supra* note 6, at 12; SCPD *supra* note 14, at 47.

conclusions. The state has 1.1 million acres of shellfish- growing waters, mainly located in Suffolk and Nassau counties of Long Island. About seventeen percent of those waters (190,000 acres) are closed to harvesting, but only twelve environmental conservation officers patrol the entire area. In other states, these same conservation officers must also perform search and rescue, boating safety and drug enforcement. The penalties for illegal harvesting range from confiscation, to a fine of $500, to six months in jail; however, the most common fine in 1981 and 1982 was only $25, and inadequate facilities made confiscation impossible. In the 1983 outbreak, the contaminated clams could not be traced because the tags were altered and mutilated, however, even without mistagging, accurate tracing is impossible because dealers commingle different shellfish stocks, and the preprinted tags often just name a prime harvesting area such as the Great South Bay. The GAO report concluded with an evaluation of three proposed solutions: first, to leave regulation to the states with the FDA as an advisor; second, to grant authority to the FDA to regulate; and third, to create a cooperative relationship between the states, the FDA and industry. The report praised the third cooperative option for its similarity to the IS SC, and expressed the hope that the ISSC would alleviate current problems. The HHS concurred with the GAO's conclusion)'[8]

The FDA also endorsed the GAO's conclusion, citing the GAO report when it withdrew its earlier proposed regulations in I 985.19 The agency explained that economic analysis had revealed the regulations to be prohibitively expensive, especially since the GAO report demonstrated that the benefits of such regulations were insignificant. The FDA announced that it would adopt the first and third options of the report by continuing to participate in the NSSP and

:18 Rep No. HRD-84-36 at 20 (1984).

:i~ 50 Fed Reg. 7797 (1985).

by cooperating with the ISSC under their memorandum of understanding. Thus, the regulation of seafood continued much as it had before; in October, a bill was proposed that would have provided authority for testing for pathogens and chemicals in seafood:[20] and the NOAA began to develop a plan for a seafood surveillance system model. As the FDA had promised, the NSSP manual was revised in 1989, as it had been in 1984.1

In 1986 the New England Journal of Medicine published several reports commenting on the shellfish-related outbreak of epidemic proportions that had occurred in 1982.222 The Journal calculated that within an eight month period, over 1000 persons in New York State suffered gastroenteritis from eating raw shellfish. Of the 1017 people who became ill, 813 cases were related to eating raw clams and 204 to eating oysters[74] Although bacteriological analysis of shellfish and stool samples failed to disclose the cause of the illness, the Norwalk virus was believed to be responsible. The study concluded that the magnitude, persistence, and widespread nature of these outbreaks raise further questions about the safety of consuming raw shellfish.∼[5] In an interesting twist on the issue, the study revealed that 26% of persons who became ill had eaten only steamed clams, which indicated that under practical field conditions, temperatures used to steam clams are often insufficient to inactivate pathogens and to eliminate the risk of illness.∼[6] The study echoed a common refrain of the GAO reports: inadequate or absent

Rep. No RCED-88-135 at 12 (Senate bill 1813 of Oct. 23, 1987).

54 Fed. Reg. 7281 (1989) and 49 Fed. Reg. 31774 (1984).

Dale L. Morse et al., *Widespread Outbreaks of Clam- and Oyster- Associated Gastroenteritis, Role of Norwalk J Thus;* 314 New Eng J. Med. 678 (1986).

::3 DuPont, *supra* note 29, at 707.

2:4 Morse et al, *supra* note 222.

– *Id.*

Id. at 680. Clams are commonly cooked until their shells open which usually occurs after

one minute of steaming. However, it takes four to six minutes of steaming in order for the internal temperature of the clam to reach levels necessary to inactivate a virus. *See also* DuPont, *supra* note 29, at 708. Another statistic is that 7 to 13 percent of poliovirus organisms added to

shipping tags made the source of shellfish difficult to trace. The study noted that although the outbreaks occurring in 1983, 1984 and 1985 did not reach the epidemic of 1982, the persistence of outbreaks demonstrated that the problem had not abated. The Journal offered one explanation:

the study of enteric virology is in its infancy; therefore, we lack the science to detect pathogenic viruses in water, shellfish or patients. ::7

In 1988, the Chairman of the Subcommittee on Commerce, Consumer and Monetary Affairs asked the GAO to gather information on the nature, extent and seriousness of seafood safety problems, thereby prompting the second GAO report on seafood within four years. The report, GAO, Seafood Safety: Seriousness of Problems and Efforts to Protect Consumers concluded that there does not appear to be a compelling case at this time for implementing a comprehensive mandatory federal seafood inspection program similar to that used for meat and poultry. ,::s The GAO emphasized the healthy interaction between the agencies that share the responsibility for seafood safety, and minimized the weaknesses of the system in place. For example, the GAO dismissed the fact that 29% of samples tested by the FDA did not comply with federal regulations for contaminants and labelling, because 78% of the noncompliant samples did not pose a direct threat to humans.:::; The GAO determined that the data did not indicate a widespread problem with American seafood, that under the current system, state and federal agencies provided adequate monitoring, and that a mandatory seafood inspection progam was inappropriate to solve existing problems with shellfish sanitation.

oysters survive 8 to 30 minutes when cooked according to various commonly used methods.

Morse et al, *supra* note 222 at 680.

– DuPont, *supra* note 29, at 708.

Rep. No. RCED- 88-135 at 5 (Aug. 10, 1988).

Id. at 3

Chapter Six

The Nineties

December 18, 1997 was the effective date for new, mandatory regulations regarding seafood. The new regulations are based on the Hazard Analysis Critical Control Point method (HACCP)– an outlook far different from previous theories of shellfish sanitation. The HACCP regulations have generated great excitement, and any discussion from a post-1997 viewpoint must be careful lest the recent regulations overshadow other important events that have taken place during this decade. Therefore, this chapter will discuss all of the events occurring in the nineties *except* for the new HACCP regulations, leaving a detailed analysis of HACCP for later chapters.

In the early nineties, concern about seafood safety hit a feverish pitch among consumers. The press seized hold of the outbreaks in seafood related illness and soon shellfish safety was a public concern. In one year, four newspapers and two television programs cited the statistic that eating fish was 25 times more likely to make you ill than dining on beef and 16 times more likely than downing poultry or pork. ~ Two states, Louisiana and California, began to require notices similar to the warnings on cigarettes, telling consumers that eating raw oysters may pose a risk to one's health)' Other states had already considered banning the consumption of raw shellfish.~ The industry and regulatory authorities were forced to respond.

Miller, *supra* note 24, at 7.

Id. at 8. Louisiana required the following wherever raw oysters are sold or on tags of sacks of unshucked oysters: Warning: consumption of raw oysters can cause serious illness in persons with liver, stomach, blood or immune system disorders. For more information, consult your physician. California required retail establishements to display a similar warning on signs. menus, table tents, or other visible places at point of sale. *Id.*

New York, for example, proposed banning the sale of raw shellfish. COSMA, *supra* note

72

FDA representatives attempted to reassure the public that seafood was indeed safe. As a retort to the widely publicized anti-seafood statistics, Acting FDA Commissioner James Benson told the New York Times, you have been severely misled.[233] Benson rejected the suggestion that NSSP needed more enforcement teeth. He argued that the states had a strong commitment to the NSSP voluntary program, because states feared that failure to comply would make other states reject their shellfish. Douglas Archer made similar arguments in his 1991 testimony before a subcommittee of the House of Representatives. Archer, Director of the Office of Seafood, argued that even though *85%* of all acute illness from seafood derives from eating raw or partially cooked molluscan shellfish, that is a very small fraction of all seafood consumed.[34] Archer also denied that the substantial number of shellfish illnesses proved the current program to be inadequate. He maintained that the FDA system solved short term issues; the long term goal of decreasing the risk of shellfish illness could only be attained if society made a commitment to stop polluting its coastlines.

In 1991, the National Academy of Sciences (NAS) published a report concluding that most seafoods are wholesome and unlikely to cause illness[7'] Despite its apparent endorsement, the NAS identified portions of the NSSP manual that needed to be strengthened: unreliable shellfish tagging; ineffective prosecution of illegal shellfish harvesters; lack of uniform criteria for evaluating the patrolling of growing areas; inconsistent product handling and maintenance of records; and absence of specific temperatures for the holding and transporting of shellfish. :3~ In response, the FDA made several changes to its safety programs It increased its monitoring of

'~' Miller, *supra* note 24, at 7.

Douglas L. Archer, *supra* note 98.

Ahmed, F.E ed, *Committee on Evaluation of the Safety of Fishery Products,* Food &

Nutrition Board, Institute of Medicine, NAS, Seafood Safety, National Academy Press, 1991.

:36 *Id*

shellfish waters, launching a special inspection program in 1991.237 It strengthened enforcement a∼zai nst illegal harvesting. It emphasized public education programs, disseminating information through the Office of Consumer Affairs, Office of Public Affairs and its Seafood Hotline.[38] The FDA was hasty to downplay its new safety programs, however: These new programs do not mean that fish are not safe food. What these new programs do mean is that FDA is enhancing its seafood inspection program to keep up with this increasingly important part of the American diet

In February 1991, the Office of Seafood was established within the Center for Food Safety and Applied Nutrition (CFSAN) in order to strengthen and provide greater focus on domestic and imported seafood safety programs.∼ The Office has numerous responsibilities:

oversight of seafood inspection programs; research and testing of methods to detect contaminants; creation of ways to prevent economic fraud; administration of the NSSP, the NSSP Manual and the ICSSL; evaluation of seafood initiatives; dissemination of information regarding regulation to the industry; creation of training programs for inspectors; and surveillance of waters, processing plants and seafood establishments.[4]' The FDA also reorganized CFSAN, allocating functions which are primarily supportive in nature among four offices that all operate under the Deputy Director for Systems and Support.∼ One of these four offices, the Office of Field

:37 Miller, *supra* note 24, at 8.

:36 Thomas J. Billy, *supra* note 57. This hotline is operated by the FDA's CFSAN. The

hotline has prerecorded messages available 24 hours a day, and public affairs specialists to answer questions during limited hours. The prerecorded menu includes topics such as women's health. product recall and seafood safety– with a special choice for raw oysters. The number is

I -800-FDA-40 10.

Miller, *supra* note 24 at 9.

24∼(Notice: Statement of Organization, Functions, and Delegations of Authority;

Establishment of Seafood, 56 Fed. Reg. 7869 (1991).

:41 FDA, *Staff Manual Guide FDA 1226.60,* Organization and Delegations Manual (1993).

available at http :// **yin.** cfsan. fda. gov/–lrd/sea-org. txt

Programs, contains a unit with expertise on the quality of shellfish growing waters and provides technical assistance for state shellfish sanitation programs.[243] The Office of Field Programs also allocates field resources, tracks field inspections, and evaluates sampling and analysis when performed.

The resources allocated to seafood increased. Food safety programs were initially staffed by 300 people, but 150 more positions were created in 1991 at a cost of $9.5 million. In the 1992 fiscal year, another $15 million was spent for 150 more positions>' The funding provided by Congress increased from $25 million in fiscal year 1990 to $40.5 million in 1993– a 60% increase. :45 Trade organizations adopted a more aggressive stance with regard to consumers. One organization, the National Fisheries Institute (NFl) launched a campaign to increase individual seafood consumption. In 1989 the NFl announced its goal of increasing the per person seafood intake from 15.9 to 20 pounds by the year 2000)

The nineteen-nineties also contained a congressional battle over which agency should have jurisdiction over shellfish. Rep. Pat Roberts, R-Kan. called this melee the surf and turf fight.[247] As of March 7, 1990, there were three bills in the Senate and six bills in the House of Representatives that addressed the increased regulation of fish.[248] Bill 2228 was proposed to establish a mandatory Federal Fish Inspection Program, based on the HACCP method The Congressional record reflects concern about selecting the appropriate agency to run this

24: Jerry A. Burke, *Center for Food Safety and Applied Nutrition's Office of S7∼tems and Support,* 48 Food & Drug L.J. 495 (1991)

243 *Id.*

44 Miller, *supra* note 24, at 8.

:45 Thomas J. Billy, *supra* note 57.

2-l∼ Miller, *supra* note 24 at 8.

:47 David S. Cloud, *Food Safety: House 'Surf and Turf Fight Dooms Fish Inspection,* 48

Cong.Q. 43, 1990

:48 136 Cong. Rec. S2228-04 (daily ed Mar. 7, 1990).

mandatory program Candidates for the position included the U.S. Department of Agriculture (USDA), the NOAA., the NMFS and the FDA. The choice of agency could not be resolved. A similar stalemate occurred in the Fish Safety Act of 1990, 5 2924.∼∼ Although the Senate and House agreed to establish a comprehensive program that extended meat inspection to fish, they were divided on which agency should run the program. The House passed a bill granting the FDA and the NOAA the responsibility, but the Senate passed the bill with the USDA in charge>' The bill died when the branches were unable to come to an agreement.

During the furor in Congress, the FDA and the NMFS gave notice of proposed rulemaking in which they would work together to establish a voluntary fee-for-service inspection program run by both agencies>'[5]' In light of the surf and turf' battle taking place in Congress, the proposed regulations seemed to be an attempt to resolve the matter administratively. ,:s: The proposed rules differed from the current NMFS program in that they intended to stimulate the use of HACCP analysis and to regulate imports as well as domestic products. The notice also proposed to remove the existing regulations at 21 C.F.R. §197 (which authorizes the inspection of canned oysters), suggesting that Section 702A of the FD&C Act was no longer in use. Perhaps in retort, Congress amended that section in 1992 and 1993. Congress redesignated Section 702A as 706, and deleted the word Agriculture from throughout the section in order to refer only to the Secretary. ∼

:49 136 Cong. Rec. S12875-01 (daily ed. Sept 12, 1990).

David S. Cloud. *Food Safety: House 'Surf and Turf Fight Dooms Fish Inspection,* 48

Cong.Q. 43, 1990.

55 Fed. Reg. 26334 (1990).

:s: Hutt, *supra* note 143, at 268.

∼' Pub. L. No.102-571, 106 Stat. 4498 (1992) and Pub. L. No. 103-80 §3(dd) (2), 107 Stat. 779 (1993).

The increased concern with shellfish gained momentum as illnesses continued to occur. For example, during November 1993, seven outbreaks occurred that were related to the consumption of oysters)[54] Forty five people suffered gastroenteritis after eating oysters harvested from Apalachicola Bay in Florida; and contaminated oysters were identified as the cause of at least 180 illnesses in Louisiana, Mississippi, Maryland and North Carolina. These outbreaks differed from previous illnesses, however, because some of the regulatory protections curtailed the severity of the harm. For example, the state health departments of Louisiana, Mississippi and Maryland notified the CDC that several outbreaks of gastroenteritis had occurred the previous week. Because of the tagging requirements, Louisiana was able to identify the source of the contaminated oysters, and illnesses in Maryland were traced to oysters harvested from the same location. Since the contaminated oysters had been distributed to at least fourteen states∼ the CDC notified state epidemiologists of potential oyster-associated illnesses. The FDA, CDC and state officials then collaborated and discovered that the oysters contained Norwalk virus. The agencies quickly pinpointed the etiology of this outbreak because specimens were collected and handled appropriately and new PCR-based [polymerase chain reaction] assays were available. ∼:5∼ The states then employed NSSP procedures regarding harvest area closures and recall procedures. The FDA issued a statement warning consumers about the contaminated oysters, and the CDC reinforced this warning with a memorandum to state epidemiologists and public health laboratory directors.

:54 42 Morbidity & Mortality Wkly. Rep 49, *supra* note 41.

Alabama, California, Florida, Illinois, Louisiana, Maryland, Mississippi, Missouri, New Jersey, North Carolina, South Carolina, Tennessee, Texas and Virginia. *Id.*

Id.

55

In 1994 the FDA offered the Interstate Shellfish Sanitation Conference (ISSC) the option of controlling Vibrio vulnificus bacterium in raw oysters by banning harvest intended for raw consumption from the Gulf of Mexico between April and October. The Conference rejected this suggestion, but performed a year-long study on time and temperature as related to the probability of Vibrio infection in at-risk populations)[57] At the next annual ISSC conference, the states proposed a requirement that oysters be refridgerated when water reaches a particular temperature; specifically, if waters attain a monthly maximum temperature greater than 84 degrees fahrenheit, oysters must be chilled within six hours of harvesting. This measure was approved **:sS**

Perhaps one can explain the conference's sudden willingness to adopt more stringent measures by analyzing events intervening between the two ISSC meetings. Between December 1994 and January 1995 a multistate outbreak of viral gastroenteritis occurred that was associated with the consumption of steamed or roasted oysters. The CDC reported thirty-four incidences of food poisoning that resembled the flu-like illness caused by Norwalk virus)[59] The oysters were harvested from Apalachicola Bay, Florida– an area that is frequently closed because waste treatment failures discharge untreated sewage into the bay.& Just recently, in 1984, authorities had closed Apalachicola Bay because 85 people contracted gastroenteritis from eating the bay's oysters. **:61** In the 1994-1995 incident, authorities closed the bay as soon as the outbreak was reported, but were surprised to discover that the fecal coliform levels in both water and oyster

:57 John Henkel, *FDA, States Collaborate For Safety's Sake,* FDA Consumer, Mar. 1996 at

27, 29-30.

:∼s *Id.*

:54 Kurtzweil, *supra* note 19. *See also* Centers for Disease Control, *Multistate Outbreak of*

I *'it-al Gass'roenteritis Associated with Consumption of Oysters– Apalachicola Bay, Florida,*

December 1994-January 1995, 44 Morbidity & Mortality Wkly. Rep. 2 (Jan. 20, 1995).

∼ *Pollution Narrows, supra* note 22, at 12. *Id.*

meat were within acceptable limits. Authorities hypothesize that increased recreational and commercial boating over the holiday season introduced Norwalk virus into the bay, but since the water met microbiological standards, the virus remained undetected. This inherent inaccuracy of microbiological testing– the disparity between fecal coliform and actual contamination– also made it impossible to determine when the bay was safe for reopening. Illnesses continued to occur up to one week after authorities closed the bay and recalled the product. The tagging, although it identified the general region of harvest, was inadequate to recall oysters from a specific site. The continued foodborne illness proved that the contaminated product had remained on the market and that cooking the oysters did not protect consumers from illness.

In January 1997, President Clinton made a radio address announcing his intentions to increase the safety of the food supply. The President broadcast that he would request $43.2 million in his 1998 budget to fund a nationwide early warning system for foodborne illness, increase seafood safety inspections and expand food safety research, training and education.∼ On May 12, 1997 Vice President Al Gore announced a five-point Administration plan of how the proposed budget would be used to increase food safety. The Administration intended to allocate $8.5 million to hire additional FDA inspectors for seafood plants, and to expand application of the seafood HACCP system to fruit and vegetable juice industries. Other objectives included developing a method to detect those pathogens now undetectable (such as hepatitis A) and creating an early warning system that would respond to outbreaks and collect data for future use

FDA, U.S Dept of Agriculture, U S. Environmental Protection Agency, Centers for Disease Control and Prevention, Report to the President, *Food Safety from Farm to Table: A National Food Safety Initiative* (May, 1997) *available at* www.cdc.gov/ncidod/foodsafe /report html.

The Vice President's plan also hoped to establish a new intergovernmental group to improve coordination between federal, state and local responses to outbreaks.

In June of 1997 a federal register was published announcing that the ISSC had decided to reconstitute the NSSP Manual of Operations in the form of a Shellfish Sanitation Model Ordinance in order to facilitate uniform adoption by the member States.)[9][2][6][3] The Model Ordinance is still a federal guideline, and is still subject to FDA policies regarding public notice and opportunity to comment, but the shift to a Model Ordinance makes the NSSP Manual more resemble the recommendations of the 1997 Food Code, published at the same time ~ The FDA plans to continue publishing revisions and interpretations of the NSSP Model Ordinance much as it has with the Manual of Operations, and it plans to use the annual meeting of the ISSC to provide a forum for public discussion.'[65] Thus, the FDA seemed to be sending the message that despite the upheavals in the control of shellfish, despite the impending mandatory HACCP regulations, the FDA's cooperative relationship with the states remains a vital part of shellfish sanitation.

:63 62 Fed. Reg 34480(1997)

~ U.S. Dep't HHS, *Food Code: 1997 Recommendations qf the US. Public Health Service,*
1997.

:~s *Id* at 34481.

Chapter Seven

The History of the HACCP Plan

From the beginning of the decade there was a flurry of activity heralding the arrival of the new HACCP regulations In 1991, Commissioner Kessler requested that the Agency study the feasibility of requiring industry-operated HACCP systems for seafood coupled with mandatory inspections by FDA that... would review the adequacy of those HACCP systems.[266] In March of 1993, the FDA announced that it was developing mandatory HACCP requirements as part of its inspection program.[267] In 1994, the Secretary of HI-IS publicized its plan to establish a food safety initiative that would require new controls in the seafood industry>'[68] The Clinton Administration supported the promulgation of regulations requiring seafood processors– particularly molluscan shellfish plants– to adopt HACCP controlsi∼o[9] In late 1995 the new rules to ensure seafood safety were issued)[7]i

The development of the HACCP system had actually started long before the stream of public announcements occurred. The principle of HACCP was born in 1959, during the development of food products for the NASA space program)[7]' Pillsbury Company was charged with the task of manufacturing food products that had an absolute assurance of safety. Several

'∼ Thomas J. Billy *supra* note 57.

∼ *Id*

:66 DIOGENES, FDA No. P94-4, FOI Services (Jan. 21, 1994).

:69 DIOGENES, FDA No. P95-9, FOI Services (Dec. 5, 1995).

:7: 60 Fed Reg 65197 (Dec. 18, 1995) and 60 Fed. Reg. 65201 (Dec. 18, 1995). *See also* Food Safety Initiative Fact Sheet, May 12, 1997 http://vm.cfsan.fda.gov/—dms/fsfact.html

Merle Pierson, *An Overview of Hazard Analysis Critical Control Points (HA CC?,' and Its*

Application to Animal Production Food Safety, HACCP Symposium, Department of Food

Science and Technology, Virginia Polytechnic Institute and State University, Blacksburg, VA

24061, *available at:* http //www cvm. uiuc. edu/haccp/symposiumipierson. html

suggestions were considered and rejected. For example, sampling for pathogenic microorganisms was inaccurate even if more than half of the food units were tested. The Zero Defects Concept was rejected because science lacked a reliable, non-destructive, testing method for bacterial pathogens. Instead, Pillsbury adopted the U.S. Army's Modes of Failure concept, which predicted places in which safety risks were likely to occur and then monitored those risk areas The army's notion of risk areas developed into the Critical Control Points used in I-IACCP plans today.

The U.S. Conference on Food Protection that took place in 1971 further publicized the principles of HACCP as a means of increasing food safety. After canned potato soup caused an outbreak of botulism in 1972, the FDA used HACCP concepts to develop regulations for low acid canned foods.[272] The new regulations moved HACCP principles from a mere scientific theory into a reality, and the transition was a success. Botulism no longer posed a threat to canned goods, and, according to the NAS, canned fish became one of the safest of seafood items. In 1985 the NAS published a report suggesting that HACCP be applied to food production beyond canned goods :73 The National Advisory Committee on Microbiological Criteria for Foods (NACMIF). which advises the USDA. FDA and NMFS (among others), reinforced the NAS' conclusion. The NACMIF recommended adoption of HACCP principles for the manufacturing of food products in

1989. 274

Although many reputable agencies endorsed the HACCP program, the FDA needed information regarding the application of HACCP principles to the seafood industry in particular.

7 44Fed.Reg. 16215 (1979), codified in2l CF.R§1]3.

:73 National Academy of Sciences, *Microbiological Criteria for Foods and Food Ingredients,* 1985. *See also* Pierson, *supra* note 271.

274 *Id.*

In 1986, NOAA operated a Model Seafood Surveillance Project (MSSP) at the request of Congress. The project conducted 49 workshops involving 1,200 industry, state and university participants.[75] The MSSP produced sixteen regulatory models for specific seafood products'[6] and manuals on how to apply HACCP to most segments of the seafood industry.[277] Seafood trade associations and Sea Grant colleges also operated pilot programs and published information on the application of HACCP to seafood)[7] For example, the New England Fisheries Development Association (NEFDA) ran a pilot program for fifteen processing firms. In 1991, the FDA and NOAA ran a joint pilot program for all types of seafood.[279] Seafood firms volunteered to adopt HACCP based controls and the FDAINOAA then conducted inspections to determine how these firms were operating under HACCP.[80] Therefore, when the administration published its regulations in 1995, a good part of the industry had either experienced or at least heard of the HACCP system. Still, the seafood HACCP program has attracted a lot of attention because it is the first time the HACCP system will be required for the processing and storage of a U.S. food commodity on an industry-wide basis.

The FDA decided to adopt a HACCP based system for several reasons. Under the program in place when the HACCP rules took effect, the FDA enforced the FD&C Act through

59 Fed. Reg. 4142 at 4150 (1994).

∼ *Id.*

:∼7 Dr. Michael Friedman, *supra* note 11

:78 The New England Fisheries Development Association (NEFDA) received federal grants

in order to help firms in the northeast implement their HACCP systems. 59 Fed. Reg. 4142 at 4151 (1994).

:7∼ *Id.*

Thomas J. Billy, *supra* note 57. In July 1992, NMIFS published a Federal Register notice announcing the availability of a new seafood inspection program based on Hazard Analysis Critical Control Point (HACCP) principles. NMIFS, *IVMFS HACCP Manual, available at* http://www nmfs.gov/iss/manual html The NMFS obtained its authority from 50 C.F.R §260. 103(c).

Kurtzweil, *supra* note 19.

periodic, unannounced, and mandatory inspections of seafood processors, packers, repackers and **v.** arehouses. With regard to imported seafood, the FDA reviewed entry documents in order to decide whether to release, visually examine or sample each shipment; a tested shipment that failed v~ as reconditioned, destroyed, or exported.[2] These inspections provided the agency with a snapshot of food safety conditions. Snapshot regulation can be ineffectual because it captures only one moment in time; it does not reveal whether the processor regularly uses safe handling practices. Furthermore, the agency must use its single snapshot to prove that the processor has done something wrong)~ In its proposed regulations, the FDA asserted that this periodic inspection had not produced a minimum level of safety.[2~] The FDA hoped that the HACCP system would remedy the weaknesses of the snapshot system by transferring to the processor the burden of demonstrating that he utilizes safe handling practices.

The new HACCP regulations also had support from the industry, the states, and academia. The industry declared that a new system was necessary in order to maintain consumer confidence in both the domestic and foreign markets. The FDA, who agreed that the existing system was inadequate, rejected the option of increasing the frequency of inspections. The NAS had recommended adoption of HACCP principles, but a voluntary I-IACCP program would do little more than the NOAA program already in place. :ss The FDA turned instead to the proposed congressional bills regarding seafood inspection. Although the bills had all failed, they shared one common element: a mandatory HACCP-based inspection system) Since the congressional battle

The FDA has the power to detain all future shipments if an importer has a history of

failure.

:33 6OFed.Reg 65096at65098(1995).

~ The FDA also argued that the tort system could not protect consumers because it was

impossible to trace illness to a particular food or food processor. 59 Fed.Reg.4 142 at 4186 (1994).

~ *Id.*

had focused on which agency should enforce the program, the FDA reasoned that HACCP principles were generally accepted. The largest seafood industry trade association, the NFl, testified at congressional hearings in support of HACCP legislation from 1989 through 1992, and in 1993 the NFl requested that the Secretary of I-il-IS not wait for congressional legislation any longer.:[57] Finally, the U.S. was catapulted into action when the European Economic Community (EEC) announced in 1993 that it intended to adopt a HACCP system. In order to export to the EEC, other countries would need equivalent manufacturing requirements. Since the U.S. is the world's largest exporter of fishery products, the EEC and other recipients of U.S-exported seafood exerted great pressure on the U.S. to adopt a HACCP system of its own)

HACCP is often described as a program that is *not* run by the government. Rather, the government uses inspections to ensure that industry systems are adequate and working. It is the responsibility of the processor to identify hazards that are reasonably likely to occur. If failure of a particular processing step would create a health hazard, that step of the process is a Critical Control Point. The processors must monitor these critical control points and record the results

for inspection. The Director of the Office of Seafood summarized the HACCP system:

HACCP requires that processors have a written plan that (1) identifies the likely hazards that could affect their products (2) identifies critical control points where a failure is likely to cause or permit the hazard to occur (3) establishes critical limits or measureable operating parameters at each critical control point such as cooking and refridgerating temperatures and (4) establishes both monitoring procedures and recordkeeping procedures to systematically record the results of the

:s∼ Dr. Michael Friedman, *supra* note 11.

:57 ∼ FedReg. 4142, at 4151 (1994).

:s∼ Thomas J. Billy, *supra* note 57. For example, Canada, Iceland, Australia and the EEC adopted HACCP principles. *See* 59 Fed.Reg. 4142, at 4152 (1994).

:s'∼ Thomas J. Billy, *supra* note 57.

Although the FDA still uses periodic inspection to enforce regulation, its inspections test whether the processor has been complying over time, because the processor must have a written plan and records proving how well critical limits have been met.

The FDA has declared that the HACCP system is authorized under both the FD&C Act (21 U S.C.§342) and the PHS Act (42 U.S.C.§264). Recall that the FD&C Act prohibits all adulterated and misbranded food in interstate commerce. :90 Section 701(a) authorizes the agency to adopt regulations for the efficient enforcement of the act. The FDA claims that the HACCP controls are efficient, as the minimum necessary to ensure that... the processing and importation of fish and fishery products will not result in a product that is injurious to health. p' If a processor fails to comply with HACCP, the food is adulterated within the meaning of §402(a)(4) and subject to regulatory action by the FDA. Note that the FDA has shifted the burden of proof to the processor, who must demonstrate that the product is not unsafe. This shift is permissible because §402(a)(4) does not require that the food actually be hazardous or contaminated in order for the FDA to exclude it from commerce. The FDA also cites the PHS Act, which prevents the spread of disease, as authority for the HACCP program. Section 361 empowers the Surgeon General (and, by delegation, the FDA) to make and enforce such regulations as the FDA determines necessary to prevent the introduction, transmission or spread of communicable disease. The tagging requirement particularly falls within the PHS Act: since shellfish harvested from non-classified waters are possible vectors of illness, identifying their source will halt interstate transport and prevent the spread of communicable disease. :s:

∼ 21 U.S.C §342, §402(a)(l). Adulterated is defined as containing any substance that may make the food injurious to health or if quality defects affect its fitness as food.

59 FedReg. 4142, at 4150 (1994).

:9: *Id* at 4169.

Chapter Eight

The Regulations Themselves

The HACCP regulations are codified in 21 C.F.R. § 123. The final regulations were published on December 18, 1995, and became effective on December 18, 1997 293 Subpart A contains the general provisions, including definitions. Molluscan shellfish are defined as any edible species of fresh or frozen oysters, clams, mussels or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle. ~ This language is important because it extends shellfish regulation to include scallops; however, the adductor exception demonstrates the same underlying rationale that shellfish require special precautions because they are eaten whole. The expansion of jurisdiction for HACCP purposes required similar amendments to other shellfish provisions. On the same day, December 18, 1995, regulations amended 21 C.F.R. § 1240 prohibiting the interstate shipment of shellfish likely to cause communicable disease. First, the amendment defined shellfish using the exact same language as § 123.3(h).[295] Second, the amendment to § 1240.60 added the word molluscanin order to distinguish bivalve shellfish from other crustaceans, such as crabs and lobsters. Finally, the amendment set forth several new requirements: shellfish must be tagged with the date, place of harvest, type and quantity of shellfish, and the identity of the harvester. Noncompliance subjects the shellfish to seizure and destruction>'[06]

:9; 60 FedReg. 65197 (Dec. 18, 1995)(effective Dec. 18, 1997).

294 21 C.F.R. § 123.3(h) (1997).

295 60 Fed. Reg. 65201 (Dec. 18, 1995), codified at 21 C.F.R. §1240.3(r) (effective Dec. 18.

1997).

2~6 21 C.F.R. § 1240.60 (b).(c) &(d) (1997).

The HACCP controls apply to all commercial seafood in interstate commerce, including both domestically produced and imported products. Seafood importers must verify that seafood is processed under HACCP standards– quite an important feature of the regulation, since more than half of this country's seafood is imported from almost 135 countries>'[97] Seafood processors, repackers and warehouses must follow HACCP.[9] Processing is defined as handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading or holding.[2~] This broad definition includes those who handle low acid canned foods, even though particular safety hazards in their processing will also be subject to 21 C.F.R. §1 ~ The regulations do not apply to those who harvest or transport fishery products without otherwise engaging in processing– such as fishing vessels. The regulations also exclude the operation of retail establishments.

The HACCP regulations require a processor to establish a HACCP plan only if the processor determines that one or more food safety hazards are reasonably likely to occur.[30] Food safety hazards may take place before, during and after harvest and they may be caused by events

97 Kurtzweil, *supra* note 19. In 1991, 3,014,819,000 pounds were imported, worth

$5,617,887,000, making the United States the world's second largest seafood importing nation.

59 FedReg. 4142, at 4151 (1994).

Kurtzweil, *supra* note 19. The FDA has declared that only processors involved in interstate commerce are covered by the regulation. FDA/CFSAN: *HACCP Regulation for Fish and Fishery Products– Questions and Answers,* http://vm.cfsan.fda.gov/—-dms/qa2haccp.html#xii

21 CFR. §123.3(k)(1).

3CX' 21 C F R. § 123(e): Products subject to other regulations. For fish and fishery products

that are subject to the requirements of part 113 or 114... the HACCP plan need not list the food safety hazard associated with the formation of Clostridium botulinum toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard

21 C.F.R. §123.3(k)(2).

~ *See* § 123.6(b): every processor shall have a HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. Under § 123 6(f) sanitation controls may be included in the HACCP plan, but need not be included if they are monitored in accordance with § 123. 11(b).

outside the processor's or importer's direct control.[33] Generally, the processor must have a HACCP plan specific to each location and each kind of fish or fishery product; however, if a few products share the same hazards, points limits, and procedures, those products may be grouped together under one plan.[3~] The FDA prefers separate plans because hazards can vary according to location, type of equipment, quality of the facility, and procedures. The proposed regulations predicted that the number of critical control points would range between two and twelve per product:~

Maintenance of a HACCP plan is an ongoing process. Each processor must reassess the adequacy of its plan on an annual basis and, additionally, any time an event occurs that may affect the quality of the plan.[306] The processor must also: monitor consumer complaints; calibrate instruments; perform end-product testing, records review and documentation; and take corrective actions. Because scientific knowledge on shellfish safety is incomplete, the government cannot expect a processor to produce an entirely safe product. For example, there is no known method to prevent the presence of Vibrio vulnificus bacteria in shellfish. Therefore, the standard used is whether processors have taken precautions that are reasonable in light of available information In the case of Vibrio vulnificus, since we do have information that temperature may limit the post-harvest growth of bacteria, processors ought to adopt temperature controls. The requirement of continuous review reassures the FDA that the processor will incorporate new controls as they are discovered.

~ 21 C FR. § 123.6(a) and § 123.6 (c)(2)(ii).

~' *Id*

59 Fed Reg. 4142, at 4156(1994).

"~ 21 CFR. §123.8(a).

The requirements for corrective actions appear in 21 C F R § 123 7 If monitoring reveals that a critical control point is exceeding its critical limits, the processor must follow either a corrective action plan he has already developed under § 123.7(b), or he must follow the procedures set forth in § 123.7(c). The procedures include segregating the affected product and reviewing the product to determine its safety for distribution. If the product is unsafe for distribution, the processor must prevent its shipment and probably must change his current HACCP plan to prevent recurrance of the deviation. All corrective actions must be documented.

Subpart C sets forth two additional requirements for raw molluscan shellfish[307]: shellfish handlers may only obtain shellfish from approved waters, and such shellfish must be properly tagged to identify their source.[308] The subpart entitled source controls requires a processor to describe in his HACCP plan how he controls the origin of his molluscan shellfish so that he accepts only those shellfish that are harvested from approved waters and tagged with information in conformity with 21 C.F.R. §1240.60(b).[306] Section F240.60 requires date of harvest, location of harvest by state and site, quantity and type of shellfish and name of harvester or registration number of harvester's vessel. The date of harvest must be accurate to the day because the safety of a harvesting area may vary within 24 hours due to tides, rainfall, winds or other events. Appropriate state control will close harvesting areas within 24 hours of discovering adverse conditions; therefore, tagging shellfish with the exact date and location ensures safe harvesting waters. Tags must identify the harvester so that he can be contacted for direct information regarding the site of harvest or for an investigation regarding tagging discrepancies. The processor's own records must indicate the date of receipt and all of the mandatory tagging

~ 21 CF R.§123.20

" Kurtzweil, *siipra* note 19.

21 CFR. §123.28

information.[3'0] As an enforcement measure, the FDA will seize and destroy shellfish that are not properly tagged.[3]

Just two months after publication of the proposed HACCP regulations, the FDA announced that it was developing a Fish and Fishery Products Hazards and Controls Guide.[31] The Guide is intended to help the industry in identifying potential hazards and developing HACCP plans. For example, the Guide lists the hazards that can affect seafood, and the control measures that will either prevent or minimize those hazards. The FDA planned for the Guide to include model plans which, if emulated, would probably be adequate to meet HACCP requirements.[313] The FDA noted that in addition to human food safety hazards, the Guide would address controls associated with quality marketability and economic fraud. The presence of these additional hazards is probably a remnant of a one-time proposal that would have required HACCP controls for risks other than human safety.[3'4] The FDA hypothesizes that in addition to helping implement HACCP plans, the Guide will help state and federal regulatory officials to evaluate HACCP plans. On April 7, 1994 the FDA published a notice of the availability of the Fish and Fishery Product Hazards and Controls Guide draft guidelines.[3'5]

21 C F.R. §123.28(c)
21 C FR. § 1240.60. The FDA also expressed the hope that § 1240.60 would support state tagging requirements by providing a uniform system with stringent punishment.

v: ∼ FedReg. 12949; Dr. Michael Friedman, *supra* note 11. 59 FedReg. 4142, at 4156 (1994).

34 The proposed regulations considered including additional hazards– such as decomposition not normally associated with illness in humans– in the HACCP controls. The Codex Committee on Food Hygeine and the NOAA believed that HACCP controls could be applied to other consumer risks without generating too many critical control points. The FDA/NOAA pilot programs also included HACCP controls beyond human food safety hazards. Nevertheless, the FDA decided not to include these additional risks, because it had created HACCP under section §402(a)(4), which applies only to substances that would render a product injurious to health.

59Fed.Reg. 16655 (1994).

The creation of the HACCP regulations has required related programs to educate the industry regarding HACCP. The need for education is actually enforced through 21 C.F.R. § 123.10, which requires training in the application of HACCP principles to fish and fishery

product processing that is at least equivalent to that received under standardized curriculum recognized as adequate by the U S. Food and Drug Administration.[3,6] To help in training, the FDA created the Seafood HACCP Alliance, which includes federal agencies, state regulatory officials, academia and industry trade associations. The Alliance develops a HACCP training curriculum for both industry and regulators; the current program entails a three day course that relies on the Hazards and Control Guide.[3,7] The USDA joined the FDA to create the HACCP Training Programs and Resources Database on the World Wide Web, in order to support the increasing educational information needs of industry and foodservice professionals in implementing HACCP programs.' The database provides listings of training programs, resource materials and consultants. Additional websites offer training progams that fulfill the training requirement of the final regulations; for example, the U.S. Department of Commerce/NOAA National Training Branch offers three day courses called HACCP Workshops for Industry.[3,9] The web also provides samples of generic HACCP plans as a starting point for processors to develop their own plans.

316 21 C.F.R.§ 123.10. For participants in the NJVWS HACCP based Program, this training requirement falls under NMFS part 1 chapter 9 section 2.

'~'~ Dr. Michael Friedman, *supra* note 11.

USDA/FDA, *HACCP Training Programs and Resources Database, available at* http //www nal . usda. gov/fnic/foodborne/haccp/haccpfly. html.

U.S Department of Commerce, National Training Branch, HACCP Workshops for Industry, *available at:* http://seafood.ssp.nmfs.gov/iss/training.html

~ *See, e.g.* http //www-seafood. ucdavis. edu/haccp/plans/oysters. htm#C2

Chapter Nine

Issues. Costs and Benefits of the HACCP Program

Right from the beginning, the industry expressed concern about how to create the newly-required HACCP plans. The FDA refused the industry's request for pre-approval of plans, arguing that sufficiency of a particular plan can only be determined under actual conditions. The FDA also contended that the combination of the Hazards and Controls Guide and the training course provided by the Seafood Alliance would provide adequate information for the industry. Still, the FDA admits that the HACCP programs will require extensive interaction between the agency and the industry. The pilot programs run by NOAA in 1991 demonstrated that the FDA must provide technical support– including a considerable amount of consultation and

∼,3'1

assistance. - Even the pilot program firms, who had volunteered and who were anxious to implement HACCP programs, discovered that identifying the hazards and critical control points

associated with their products was a difficult taski∼

Another issue worrying the industry is the cost involved with implementing a HACCP plan The FDA has difficulty quantifying the feedback it receives from pilot programs; however. some reactions seem fairly consistent. Costs were often greater than expected[33] and the FDA had underestimated the amount of time needed to prepare a HACCP plan.∼[4] The FDA calculated that there are 4,846 domestic seafood manufacturing plants that will be affected by the proposed

59 FedReg 4142 at 415 1(1994)

3:: *Id*

3:3 Second Interim Report of Observations & Comments (October 31, 1997) *available at*

http://vm.cfsan.fda. gov/–dms/haccp-3 . html

3:4 Final Regulatory Impact Analysis: Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed.Reg. 65096-01 (1995). FDA revised estimates to allocate 24 person hours to preparing a simple plan and 144 hours for a complex plan.

rule< and that average plant costs will range from $6,400 to $23,000 for the first year, and from $4800 to $13,000 for subsequent years.[32] Costs for the first year were divided as follows: 33% for compliance with sanitary provisions; 36% for monitoring and recordkeeping; and 31% for equipment, temperature indicators and temperature recorders. Additional costs included training the HACCP team and employees, time and personnel needed to monitor, create and keep records, consulting costs and equipment installation.

Nevertheless, when the FDA performed a regulatory impact analysis as required by Executive Order 12866,327 the agency concluded that the regulatory option selected was the least burdensome option to accomplish the goal of controlling all physical, chemical and microbiological hazards reasonably likely to be present in seafood.[32] In the pilot programs, firms noted that they experienced more effective and efficient operations, higher level of confidence in product safety, and greater involvement and safety awareness by employees. The FDA catalogued further benefits of HACCP: decreased illness and death, reduced enforcement costs, increased consumer confidence, better process control, improved employee morale, and continued exports. Unfortunately, even after the regulations are implemented it will be difficult to evaluate the success of the HACCP program. Although a decrease in seafood-borne illness would be certain success– and the FDA predicts a decrease of 5,000-19,000 cases of seafood illness and deaths per year[329]– the inaccuracies of illness reporting are making the FDA look for surrogate ways in which to evaluate its program.[33]

3:5 ∼ FedReg. 4142, at 4187 (1994).

Final Regulatory Impact Analysis.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Final Regulatory Impact Analysis.

∼ *Id*

The FDA also performed a Regulatory Flexibility Analysis regarding the effect of the regulation on small businesses.[33'] In the context of shellfish regulation, attention to small seafood processors is critical because such small businesses produce the vast majority of seafood types that account for most of the food-associated reported illnesses[332]– *i.e.,* molluscan shellfish. The cost of implementing a HACCP program is determined by the complexity of processing and hazards, not by the size of the business or its output.[333] Therefore, any fixed costs will affect small businesses disproportionately. The FDA estimated that for each 1% increase in the price of seafood, 140 small processors will go out of business; nevertheless, the agency concluded that the effect on small businesses was acceptable.[3~] The FDA argued that increased consumer confidence could increase the demand for seafood, which in turn would counter any price increase. The FDA also hypothesized that current proposals to apply HACCP regulations to meat and poultry would similarly raise meat and poultry prices; therefore, consumers will not substitute other foods for shellfish. Finally, the FDA believed that the Hazards and Controls Guide, the two year window in which to comply, and the aid of the Seafood Alliance meant that small businesses could meet HACCP requirements without undue hardship. ~

39 59 FedReg. 4142, at 4188 (1994). By attributing different costs according to the severity of the illness, the FDA values the safety benefits of I-IACCP at $1 5-17 million per year. *Id.*

~ Dr. Michael Friedman, *supra* note 11. The difficulty of judging program success by illnesses is illustrated by the case of neurotoxic shellfish poisoning (NSP). NSP is primarily associated with recreational fishing; therefore, these illnesses are not likely to decrease. 59 Fed Reg. 4142, at 4188 (1994).

Regulatory Flexibility Act (Pub. L. 96-3 54).

33: Final Regulatory Impact Analysis. The FDA estimates that 80% of the seafood processors covered by HACCP regulations are small, which is defined as less than $1 million annual gross revenue for nonshrimp firms. 59 Fed.Reg. 4142 at 4189 (1994).

Final Regulatory Impact Analysis.

~ *Id.*

~ *Id*

One can imagine that in the FDA's cost-benefit analysis of the HACCP system, the agency placed high value on ending the accusation that inspections are not performed with enough frequency. Historically, the perceived inadequacy of the snapshot inspections subjected the FDA to much criticism. For example, many would cite the statistic that although 60% of seafood consumed in the U.S. is imported, the FDA physically examines less than *5%* of all lots of seafood. The FDA has defended the small number of inspections, asserting that lots vary in size, the FDA targets by experience, and domestic laws will subject the food to further processing within the U.S. The FDA claims that tabulation of the actual number of inspections is impossible because the number of state inspections is unknown and incompatibility between federal and state programs prevents the integration of federal and state data. Finally, the FDA cites the NAS for the principle that increased frequency of inspections would have no bearing on safety. Thus, the FDA's cost-benefit analysis would never advocate simply increasing inspections.

With the HACCP program, however, the FDA may resolve the frequency-of-inspection debate. While inspection of HACCP plans will continue as part of routine, mandatory plant examinations,[336] the HACCP requirements will make these inspections more meaningful. One snapshot will reveal whether a processor has maintained adequate sanitary precautions, and it will predict with some accuracy whether contamination will occur in future. Thus, it is the processors HACCP plan that will prevent adulterated products from reaching the consumer– not an FDA agent inspecting each product. Additionally, HACCP inspections are more easily coordinated with the states so that enforcement resources and subsequent data can be shared. The FDA calls the HACCP system leveraging its resources: while the number of inspections themselves will not increase, they will make a bigger difference in the safety of seafood.

3k $\sim$ FedReg. 4142, at 4156 (1994).

Despite the FDA's faith in the benefits of I-IACCP-based safety measures, one must not overlook the program's limitations. The final regulations apply only to processors; thus, they exclude fishing vessels, common carriers and retail establishments.[337] Poor handling during transport or retail can certainly create health hazards; for example, time and temperature during transport and sanitary practices at the retail level fundamentally affect seafood safety. The FDA admits that seafood products have a relatively short shelf-life once they reach restaurants, that they are subject to cross-contamination, and that a significant number of reported acute health problems were likely linked to handling and preparation practices in food service establishments. n Nevertheless, because the FDA has never directly regulated fishing vessels, common carriers or retail establishments, the agency doubted whether a HACCP system would be appropriate in those venues. The agency argued that the sheer number of vessels, carriers and retail establishments would overwhelm any existing or foreseeable Federal regulatory structure. 'p Instead, the FDA hoped that processors themselves would enforce a HACCP program for transportation and retail. Since HACCP requires that processors monitor the quality of the raw materials they receive, processors could potentially demand that their suppliers use safe handling practices. Retailers are also urged to adopt HACCP principles in the FDA's 1997 edition of the Food Code, which is not binding but serves as model legislation for state and territorial agencies that license and inspect food service establishments, food vending operations and food

∼ Dr Michael Friedman, *supra* note 11. 59 Fed Reg. 4142. at 4154 (1994). Dr Michael Friedman, *supra* note 11.

∼' Kurtzweil, *supra* note 19.

Ironically, it is the FDA itself who cast doubt upon the wisdom of exempting vessels and retail establishments from HACCP requirements. Despite the FDA's now- vigorous defense of its decision, the agency was not always so certain of how to approach the vessel/retail issue. In fact, in the original proposed regulations the FDA asked for public discussion on whether the agency were right to rely on processors for the enforcement of safe handling practices>'[4,] The FDA welcomed input on whether HACCP would be effective as applied to transportation companies. The agency also called the model food codes a tentative approach and requested comments on how to regulate the retail sector. The FDA declares that the HACCP program will make great changes, that it will significantly reduce illness– but vessels, carriers and retail establishments may very well continue to operate as if HACCP were never enacted.

Another uncertainty of the HACCP system is how state and federal regulation will actually overlap. For example, when asked whether HACCP supersedes NSSP, the FDA's answer was that states enforce NSSP by establishing regulations, and processors of raw molluscan shellfish must still comply with state lawY∼ The NSSP has been revised to incorporate HACCP requirements, and changes in state regulations should soon follow, but it seems questionable whether the language of HACCP, NSSP and state regulations will always be a perfect match. Take, for example, the receipt of raw molluscan shellfish from unapproved growing waters:

§ 123.20 of the **HACCP** regulations sets forth requirements regarding receipt of shellfish. Section 123's requirements are mandatory if processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.[343] Thus, if a

59 Fed.Reg. 4142, at 4154 (1994).

;4: FDA/CFSAN: *HACC'P Regulation for Fish and Fishery Products– Questions and Answers, available at:* http://vm.cfsan.fda.gov/.—dms/qa2haccp html#xii

∼ 21 C.FR. §123.20

processor will be heat-treating the shellfish sufficiently to destroy pathogens, for HACCP

purposes he need not comply with § 123.28 regarding approved sources. However, State statutes do not at present allow harvesting from unapproved waters unless molluscan shellfish will be

relayed or depurated. Therefore, despite the HACCP exception, it seems unlikely that processors could receive shellfish from unapproved waters without violating the state regulations. This

creates a dual regulatory system whenever HACCP and state requirements do not match perfectly.

The HACCP program will not eclipse all past regulations. It is undisputed that the new

requirements do not affect every participant in the shellfish industry, and the FDA has insisted that HACCP will not replace the function of the states) Indeed, HACCP requires a shellfish control authority– either federal or state– to classify harvesting areas, enforce harvesting controls and

certify shellfish processors.[345] After HACCP, the FDA will continue to perform many of its past functions: it will set standards for seafood contaminants; it will promulgate Good Manufacturing Practices and Model Food Codes;[3] and it will provide financial support to the states.[347] Despite the many benefits of the new regulations, HACCP remains an imperfect solution. The shellfish

industry contains small, seasonal businesses that are dominated by manual labor; they may find it difficult to adopt the highly technical HACCP requirements And, even a heavy burden on

processors to demonstrate the safety of their incoming materials may not be adequate to deter them from cheaper– and riskier– seafood.

CF SAN handout, 1995, *available at:* http://vm.cfsan.fda. gov/—lrd/seaovr. txt ∼' 21 CFR. §123.3(o)

∼ CFSAN handout, 1995

Thomas J. Billy, *supra* note 57. The total expenditure by state, federal and local regulator∼ bodies for regulation of seafood is estimated to exceed $100 million per year.

Hopefully, the HACCP system will succeed in preventing the outbreaks described in previous chapters. The tagging requirements should write a new ending to the stories about auents who could not find the source of contaminated shellfish. The documentation requirements should repair the inadequacies of snapshot inspections. The shift in burden of proof and increased enforcement power may persuade processors to comply with sanitation precautions. Thus, even if the HACCP program is not the final word on shellfish regulation, it promises to be a high point in the history of seafood safety.

Chapter Ten

Postscript

An historical survey is an odd creature. The peaks and valleys that scar each decade suddenly become a gentle slope when one steps back to survey the landscape. Events such as the enactment of HACCP regulations become not a phenomenon, but a logical step in the evolution of shellfish safety. Since 1906 the federal government has been involved in protecting the public from contaminated shellfish. Perhaps the mandatory inspection program that appeared ninety-one years later took too long to evolve; perhaps it was only after the natural resources were irretrieveably polluted that the program became indispensable. Regardless, the HACCP program is not the single, defining, moment in a century of shellfish regulation.

In 1910, at the very beginning of shellfish regulation, one author had formed a connection between shellfish and disease. He already knew that shellfish were affected by the cleanliness of surrounding water. He knew that bivalves sifted out bacterium in filter feeding, that eating raw shellfish was particularly risky, and that pollution from cities posed a great danger. However, he

found little sympathy for his concerns:

It is a curious fact that many persons who may be willing to accept the truth of statements on the nature of infectious diseases and their transmission, yet regard the dissemination of such knowledge almost with resentment, apparently because it is disturbing to peace of mind, and may have a tendency to interfere with careless habits. Who has not heard remarks of this nature: – Our fathers lived in comparative safety, but science has surrounded us with deadly germs... The church, the theater, the cars are germ-laden, and we are not able to draw a comfortable breath. Away with such nonsense! We must live, and the germ theorists are trying to make existence impossible.[348]

∼ James Lawrence Kellogg, Shell-fish Industries (1910)

There has been no single, defining moment in this century of regulation; but if a moment had to be chosen, it would be the instant that society placed importance on shellfish safety. Far more momentous than any regulation was the day that the public did not regard dissemination of information with resentment. The day that science turned its attention to the etiology of outbreaks and the ability of shellfish to carry pathogens, the day that shellfish sanitation became a pressing issue, and the states, industry and federal government formed a cooperative program to combat shellfish-related illness– those are the events that shape the history of shellfish regulation.

Each new regulation is enacted with high hopes and great expectations. Perhaps the HACCP program will indeed prevent the illnesses and outbreaks that dominate this historical survey– but no inspection regulation can be expected to resolve one fundamental problem of shellfish safety: until society agrees to halt pollution, shellfish will never be safe. It is conceded that the new regulations are necessary to monitor the post-harvest handling of shellfish. It is admitted that naturally-occurring pathogens contaminate even those shellfish harvested from pristine waters. But if society continues to pollute, the acres of water closed to harvesting will continue to increase. Re-laying is useless if there are no clean waters. A regulation may prevent every single polluted clam from reaching the consumer, but if no unpolluted clams exist, how hollow the triumph. The shellfish industry shares a community resource, and unless society ensures the quality of that resource, regulations can only temporarily solve health issues. Perhaps the single, defining moment of shellfish regulation lies in the future: on the day we can finally promise that the pollution of shellfish waters has ended.