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ABSTRACT

GLEND A. LEWIS. A Survey of the Organization and Management of State Shellfish Programs.
(Under the direction of DR. MORRIS A. SHIFFMAN)

The operational and intergovernmental practices of state shellfish programs were examined to view the current status of these state programs. A questionnaire was used to perform the study. States are currently in compliance with directives and requirements of the Interstate Shellfish Sanitation Conference. Obstacles discovered to efficient and effective state implementation of these duties include insufficient resources, state doubt in the validity of established bacteriological standards, and a general lack of legislative and public awareness. An effective approach to aid in the coordination of state efforts under the Conference is the full exchange of information among neighboring states. A strong need exists for a realistic and continuing evaluation of the state role in shellfish management.

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DEDICATION

To my mother, Mrs. Olive Lewis and my father,
Mr. Lucien Lewis, whose love and encouragement helped make
it all possible.

UNIVERSITY OF CALIFORNIA

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CHAPTER I

INTRODUCTION

Molluscan shellfish have provided an important source of food for the United States since colonial times while simultaneously serving as an important economic base for many coastal communities. In the early 1900's oyster production along the Gulf and Eastern coasts of the United States was a major resource, often exceeding 100 million pounds per year. This compares to 53 million pounds produced on all coasts in 1975 (Clem, 1978).

Shellfish are found predominantly in estuaries where freshwater mixes with saline coastal waters. Estuaries provide critical habitats for shellfish, while also serving as nursery areas for an estimated 60 percent of the nation's living marine resources. These valuable resources require protection and monitoring to ensure the health of the Nation's shellfish population.

Shellfish exposed to polluted water may become agents of gastroenteric diseases. The quality of the water in which shellfish are grown presents the primary hazard to the consumer. Shellfish, if contaminated, present a potential health hazard to the consumer because 1) of the shellfish's

ability to filter and concentrate pathogenic microorganisms and toxic substances from the environment; 2) the natural habitat of shellfish is almost universally subject to some degree of industrial, residential, or animal pollution; 3) shellfish are frequently consumed either raw or partially cooked; 4) harmful substances can be introduced into shucked meats due to the nature of the shucking process; and 5) inadequate refrigeration of packed raw shellfish provides an excellent growth medium for bacteria (Federal Register, 1975).

In order to provide adequate consumer protection and minimize potential health hazards, sanitary controls in the management of shellfish must encompass all phases of shellfish growth, production, and distribution -- from the growing area through all aspects of harvesting, processing, packaging, storage, and distribution.

Currently, our shellfish resources are managed through 23 State shellfish programs throughout the United States. These State programs are, in turn, managed under the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference.¹

The National Shellfish Sanitation Program is a voluntary cooperative program between the federal government, shellfish-producing states, and the shellfish

¹A discussion of these programs is in Chapter III.

industry. The program has as its mission the protection of the consumer from shellfish-borne illness, which is accomplished through the setting forth of guidelines for the management of state shellfish programs.

Upon its creation in 1982, the Interstate Shellfish Sanitation Conference replaced the National Shellfish Sanitation Program. Like the National Shellfish Sanitation Program, the Interstate Shellfish Sanitation Conference is a tripartite organization with federal, state, and industry representation. The Interstate Shellfish Sanitation Conference, however, is more formally organized, with a constitution, by-laws, executive board, and task forces.

States manage their programs with the aid of uniform sanitation standards established for each phase of bringing safe shellfish to the consumer -- encompassing the growth, harvest, processing, packaging, storage, and interstate shipping of shellfish. Criteria and standards for the sanitary control of shellfish are contained in the National Shellfish Sanitation Program Manual of Operations, Part I, Sanitation of Shellfish Growing Areas and Part II, Sanitation of the Harvesting and Processing of Shellfish. These standards have been formally adopted by the Interstate Shellfish Sanitation Conference and by State agencies, which incorporate them into state laws or regulations.

Variations exist among the participating states in the operational and intergovernmental practices used to

implement these standards. Such variations exist for several reasons. Some are an inevitable result of differences in geography or resources (specific species abundance and distribution). Others result from differences in organizational structure, the availability of funds, the priority level of the shellfish issue in state legislatures, or the amount of available staff to perform the varied tasks required. The variations themselves are not necessarily detrimental, however the nature and extent of the variations may increase the risk of safe shellfish not reaching the consumer.

Purpose of the Study

The purpose of the study is to determine:

- 1) What variations exist among the 23 shellfish producing states in the operational and intergovernmental practices used by them to accomplish uniform shellfish control measures, as set forth by the National Shellfish Sanitation Program;
- 2) What variations in these practices seem to be undesirable in terms of inefficiency in management; and
- 3) What specific variations exist in these practices that could endanger shellfish consumption.

Hypothesis

The greater the degree of variability, as well as the frequency of variability among states in their operational and intergovernmental practices when implementing uniform sanitation standards, the greater the potential risk to the consumer of obtaining unsafe shellfish.

Statement of the Problem

State organizational and management practices, with regard to ensuring the safety and quality of shellfish, are inconsistent throughout the 23 shellfish-producing states.

Thesis Statement

Inconsistencies in State operational and intergovernmental practices in implementing uniform shellfish control measures, as set forth by the National Shellfish Sanitation Program, have the potential to jeopardize the safety of shellfish consumption.

CHAPTER II

STUDY SPECIFICATIONS

Objectives

- 1) To determine whether states are functioning within the general framework of the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference;
- 2) To determine what differing techniques and strategies State shellfish programs utilize in carrying out their National Shellfish Sanitation Program and Interstate Shellfish Sanitation Conference duties;
- 3) To determine whether a stronger or different State role is needed to regulate shellfish; and
- 4) To identify major obstacles to State action for regulating shellfish sanitation.

Limitations and Constraints of the Study

Limitations: The major limitation of the study is the willingness and ability of the key State shellfish regulatory officials contacted to respond at all, to respond in a timely fashion, and to respond accurately to inquiry about the management of their state programs.

Constraint: The major constraint is the size of the study. Consideration is given to the Interstate Shellfish Sanitation Conference participant states which are shellfish-producing states.

CHAPTER III

REVIEW OF RELEVANT LITERATURE

Introduction

The purpose of this chapter is:

- 1) to inform the reader of developments in food safety and protection by reviewing the first federal food laws;
- 2) to inform the reader of developments in shellfish regulation, in particular; and
- 3) to inform the reader of the current status of the control of shellfish resources in the United States.

Presented is a brief legislative history of food control in the United States, in general, with emphasis on the history of shellfish control and its application to current shellfish control practices.

History and Background

Regulation of Food in the United States

Today the United States food supply is generally recognized as one of the world's safest. It is also one of

the most complex. Numerous federal programs² exist through which the government is involved in food regulation. To fully appreciate the complex structure of food and drug control today requires some knowledge of the history of federal food protection.³ Two major federal food laws are covered: the Food and Drugs Act of 1906 and the Federal Food, Drugs, and Cosmetic Act of 1938.

The original incentive for the beginning of food processing regulations was the recognition and realization that the consumption of impure foods contributed to many cases of illness and even death. An 1879 bill introduced in Congress "for preventing the adulteration of articles of food and drink" (Congressional Record, 1879) marked the first attempt at Federal control of food for protecting the consumer. It also initiated a 27-year battle, resulting in the enactment of the Pure Food and Drugs Act of 1906. This act defined "adulterated foods" and instituted the first food inspection program to apply to all foods in interstate commerce.

In the years following its enactment, several limitations of the 1906 act were noted. The Chief of the Bureau of Chemistry (later to become the Food and Drug

²Major food safety related programs can be seen in Appendix 3.

³A chronology of federal food safety and related legislation can be seen in Appendix 4.

Administration) included the following limitations in his 1917 annual report (1917 Report of the Bureau of Chemistry, 1951):

- 1) lack of legal standards for foods;
- 2) lack of authority to inspect warehouses;
- 3) need for greater flexibility to prescribe the disposition of imports; and
- 4) no ban on the addition of poisonous substances to food.

As a result, between 1906 and 1938 the Food and Drugs Act was amended several times in attempts to strengthen the law.⁴ A 1933 bill to supplant the "outworn mechanism" of the 1906 law outlined several new provisions which would permit increased regulation over foods (1933 Annual Report). Stated provisions included:

- 1) Informative labeling would be required;
- 2) The promulgation of definition and standards for food, which will have the force of law, would be authorized;
- 3) The prohibition of added poisons in foods or the establishment of safe tolerances would be provided for;
- 4) The operation of factors under federal permit would be prescribed where protection of public health would not be otherwise affected; and

⁴See Appendix 4.

5) More severe penalties, as well as injunctions, in the case of repeated offenders would be prescribed.

Opposition to this bill occurred and a succession of Congressional bills followed in the next four years. These events culminated on June 25, 1938 when the President signed Public Law 717, the Federal Food, Drug, and Cosmetic Act of 1938, into law. This was the first major statutory revision of the 1906 act and has subsequently been amended several times.⁵

The Food, Drug, and Cosmetic Act (21 USC 301-392) is the basic food and drug law of the United States. With its numerous amendments it is the most extensive law of its kind in the world. Many State food laws are patterned after the federal law, and some have provisions to add automatically any new federal requirements.

The Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act as amended (21 USC 301) has responsibility to ensure that foods, including fish and shellfish, shipped or received in interstate commerce are safe, are processed under sanitary conditions, and are not adulterated. If the Food and Drug Administration finds unsanitary plant conditions, adulterated products, or a contaminated product, it can take any of the following legal actions: "(1) prosecute anyone who violates the provisions

⁵See Appendix 4.

of the act; (2) enjoin a plant or individual to correct the unsanitary plant conditions; and (3) seize a food that is adulterated or contaminated when introduced to or while in interstate traffic." (1979 Report) In practice, these powers are seldom used by the Food and Drug Administration to insure that fresh or frozen shellfish are safe. Instead, the Food and Drug Administration relies on its participation in the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference to achieve its purpose.

Regulation of Shellfish in the United States

Prior to 1925, United States shellfish resources were not a federal priority. The value of these resources, however, was reflected in State control measures, such as bacteriological sampling of shellfish, inspection of processing plants, and some inspection of shellfish growing areas. New York state passed legislation as early as 1715. Other states to pass early legislation were New Jersey (1730) and Rhode Island (1734). Such legislation was directed to the regulation of harvesting, with a goal to protect the renewable shellfish resources in order to assure a continuing supply.

Public health controls of shellfish became a national concern in the United States in the late 19th and early 20th century, upon the realization by public health authorities

of a large number of outbreaks of illnesses associated with consuming raw oysters, clams, and mussels. In the winter of 1924, there occurred in New York City, Chicago, and Washington, D.C. a widespread typhoid fever outbreak traced to the consumption of oysters contaminated by sewage pollution. In response to the seriousness of the outbreak and the loss of confidence in the shellfish industry, local and State public health officials and the shellfish industry requested that the Surgeon General of the United States Public Health Service develop necessary control measures to ensure a safe shellfish supply to the consumer.

In accordance with this request, the Surgeon General called a conference of representatives from State and municipal health authorities, State conservation commissions, the Bureau of Chemistry, the Bureau of Fisheries (now the National Marine Fisheries Service) and the shellfish industry. This historic conference was held in Washington, D.C. on February 19, 1925 (US Public Health Service, 1925).

It is important to note that many federal and State agencies were represented, as well as key members of the shellfish industry. This cooperative approach was the first of its kind ever attempted toward federal food protection and would set a precedent for future shellfish control. Under the cooperative approach with State control agencies, the Public Health Service would provide assistance and

promote the development of basic control practices, which the states would adopt. The members of the conference recommended eight resolutions for the sanitary control of the oyster industry (Federal Register, 1975). The principles of shellfish sanitation resulting from this conference included:

- 1) "The beds on which shellfish are grown must be determined, inspected, and controlled by some official State agency and the US Public Health Service."
- 2) "The plants in which shellfish are shucked or otherwise prepared or packed by the shipper must be controlled by some official State agency and the US Public Health Service."
- 3) "There must be such governmental supervision and such trade organization as will make plain the source of shellfish and will prevent shellfish from one source being substituted for those from another source. This will be chiefly a problem of the individual State."
- 4) "The methods of shipping must be supervised, inspected, controlled, and approved by the proper official federal and State agency."
- 5) "The product must conform to an established bacterial standard and must meet federal, State, and local laws and regulations relative to

salinity, water content, food proportion and conform to the Pure Food Laws standards."

The public health controls and principles formulated at the 1925 conference became the basis of the National Shellfish Sanitation Program.

To implement the program, members of the 1925 conference agreed to publicize those states which had adopted the principles, in what is known as the Interstate Certified Shellfish Shippers List. The producing states would issue "Certificates", i.e., a permit to operate, to those shellfish shippers meeting agreed upon sanitary standards.

None of these matters were formalized in federal regulations, but relied upon a voluntary approach to convince state officials of the importance of adopting control practices. The voluntary approach relies on the enactment of State laws along with federal technical support and industry participation. The National Shellfish Sanitation Program has been entirely dependent upon this approach for over 75 years.

To further implement this cooperative, voluntary program, each partner accepted responsibility for certain procedures toward controlling shellfish growing areas and maintaining sanitary conditions in shellfish processing plants (US Department of Health and Human Services, 1986):

*Each shellfish shipping state agreed to adopt adequate laws and regulations for sanitary control of the shellfish industry, make sanitary surveys of growing areas, delineate and patrol restricted areas, inspect shellfish plants, and conduct such additional inspections, laboratory investigations, and control measures as necessary to insure that the shellfish reaching the consumer had been grown, harvested, and processed in a sanitary manner. Along with this, states issued numbered certificates and forwarded copies of the interstate certificates to the Food and Drug Administration.

*The Food and Drug Administration agreed to serve in an advisory capacity reviewing State programs and suggesting improvements. Included in this was the inspection of a representative number of shellfish processing plants.⁶ On the basis of information obtained, the Food and Drug Administration would endorse, or withhold endorsement, of each State program. A list of valid interstate shipper certificates issued by State control authorities with Food

⁶Guidelines for federal appraisal of State Shellfish Sanitation programs were adopted in 1965 and can be found in US Department of Health, Education, and Welfare, Public Health Service, Division of Environmental Engineering and Food Protection, Shellfish Sanitation Branch. National Shellfish Sanitation Program Manual of Operations, Part III, Public Health Service Appraisal of State Shellfish Sanitation Programs, 1965. This manual is no longer used in federal evaluation of state programs. Parts I and II of the Manual of Operations are used.

and Drug Administration endorsed programs was published monthly.

*The shellfish industry agreed to harvest and process shellfish under sanitary conditions. This included obtaining shellfish from safe sources, providing plants which met the agreed upon sanitary standards, placing the proper certificate number on each package of shellfish, and keeping and making available to the control authorities records which would show the origin and disposition of all shellfish.

The basic public health principles formulated in 1925 for the National Shellfish Sanitation Program have remained unchanged. Program procedures, however, have been periodically updated and improved.⁷

In 1954, the first of ten National Shellfish Sanitation workshops was held in Washington, D.C.⁸ The purpose of the workshop was to provide a forum for the three Program participants to: 1) recommend changes in the program's administrative procedures and technical standards; 2) review

⁷A list of previous editions of Manual of Operations for the National Shellfish Sanitation Program can be seen in Appendix 5.

⁸National Shellfish Sanitation Program Workshops were held in 1954, 1956, 1958, 1961, 1964, and 1968 under Public Health Service sponsorship. In 1971, 1974, 1975, and 1977 the Food and Drug Administration sponsored workshops as part of its administrative role in the National Shellfish Sanitation Program.

research needs and ongoing projects; 3) discuss state program activities and emerging problems; and 4) describe new federal legislation, regulations, and programs (National Shellfish Sanitation Program, 1977).

In 1968, responsibility for the shellfish sanitation program was moved from the Public Health Service to the Food and Drug Administration. The change in administration brought with it drastic changes for the National Shellfish Sanitation Program. The Food and Drug Administration's enforcement orientation led to problems with state programs. Various state programs began to diverge from the established standards. The Food and Drug Administration threatened not to endorse the states' programs. However, since participation in the program is voluntary, the federal arm of the program has no legal authority to enforce state compliance with the established standards. Removal of federal endorsement of a state program was the only action available to ensure the safety of shellfish as a food source.

Removal of federal endorsement of a state program results in the decertification of that state. With decertification, any shellfish originating in state waters are no longer allowed to be transported in interstate commerce. Decertification also removes the power of states to issue certificates, thus preventing shellfish dealers from operating. The names of these dealers are also removed

from the Interstate Certified Shellfish Shippers List. Once removal from this list has occurred, other states agree to no longer accept shellfish from the decertified state. Such actions facilitate state compliance with National Shellfish Sanitation Program guidelines and facilitates the prevention of shellfish from the decertified state ever reaching the market.

Accordingly, the Food and Drug Administration proposed formal Federal regulations for a "National Shellfish Safety Program" in the Federal Register (1975). The proposed regulations were to legalize the National Shellfish Sanitation Program and give the Food and Drug Administration authority to administer the program under federal mandates.

Evaluation of comments received in response to the proposed regulations led the Food and Drug Administration to determine that National Shellfish Sanitation Program goals would not likely be reached through the promulgation of federal regulations. Subsequently, revision of the 1965 Manuals of Operation was chosen as a better approach to strengthening the program (Federal Register, 1985).

During this period many shellfish producing states were concerned that some state shellfish control agencies were not adopting the revisions in a uniform and timely manner. For this reason, other methods for strengthening the program were also sought. The primary method chosen was the creation of a voluntary organization patterned after the

National Conference of Interstate Milkshippers program. This program has been successful since 1950 in assuring a nationwide safe and wholesome milk supply and was used as a model for developing the Interstate Shellfish Sanitation Conference.

Current Situation

The Interstate Shellfish Sanitation Conference

In 1982 the Interstate Shellfish Sanitation Conference was formed in Annapolis, Maryland. Constitution, By-laws, and Procedures were adopted establishing "a variable organization with the stated purpose of fostering and improving the sanitation of shellfish through interstate cooperation and through uniformity of State shellfish programs." (Interstate Shellfish Sanitation Conference, 1982) The organization allows for input from State regulatory officials and industry under the health umbrella of the Food and Drug Administration.

To achieve its goal, the Interstate Shellfish Sanitation Conference agreed to adopt a set of guidelines for the sanitary control of shellfish. At the first annual meeting held in 1983, the Interstate Shellfish Sanitation Conference adopted the National Shellfish Sanitation Program Manual of Operations, Parts I and II, 1965, and formal procedures that enabled it to adopt changes in the Manual.

In addition, the business of the Conference is met through the existence of an executive board, task forces, committees, and annual meetings, as provided for in the constitution and by-laws.

Committees are developed pertaining to the specific issue referred to them by the Task Forces. Routinely, committees are set up thirty to sixty days after the annual meeting. Experts in the area under consideration by the committee are sought as committee members. Initially, members are obtained on a voluntary basis. If, however, after this first approach a committee lacks the number necessary to accomplish its goals, members are solicited by the Interstate Shellfish Sanitation Conference chairman.

Committee members meet throughout the year, usually by phone. Old, unresolved issues carried over from the previous annual meeting are deliberated throughout the year. On the Sunday and Monday prior to voting at the next annual meeting, the committee members meet to finalize their position on the issues prior to submitting them to the appropriate Task Force. On Tuesday and Wednesday prior to voting, the Task Forces meet and consider the old issues submitted to them by committee. At this point, the issues are either adopted and a report submitted to the general assembly or referred back to committee for further deliberation. On Thursday, voting by State delegates takes place.

At the annual meetings, voting State delegates have the authority for adopting policies, procedures, and guidelines. New items to be voted upon are submitted to the appropriate Task Force which deliberates and takes one of two courses of action: 1) if the Task Force can not resolve the points in question, it refers the issues to committees for further deliberation (these are now old issues to be deliberated upon for the next annual meeting); or 2) if the Task Force can resolve the points in question it issues a recommended action to the voting delegates. Consideration of the recommendations and subsequent voting takes place in the open general assembly. To assure that adequate consideration by the Task Force is given to each suggestion or proposal, new items must be submitted three to four months prior to the next Conference meeting.

Once a Task Force's findings are accepted, the proposal is forwarded to the Food and Drug Administration for review to insure its consistence with existing federal laws, regulations, and Conference policies and procedures.

Following Food and Drug Administration approval, states begin incorporating the recommended policies, procedures, or guidelines into each State's regulations or laws through their own Administrative Procedures. Although State participation is voluntary, the Food and Drug Administration can enforce the adopted requirements through its regulatory control of interstate commerce.

Conference activities are directed by an executive board. Members of the board include elected representatives of State and industry on a specified regional basis, and a Food and Drug Administration representative. Only State representatives, however, have voting rights on the board, as well as on the task forces.

The Food and Drug Administration serves, within guidelines agreed upon in a Memorandum of Understanding with the Interstate Shellfish Sanitation Conference "as an evaluator of the State's program compliance with the Interstate Shellfish Sanitation Conference national program, a training and standardization agency, and as a channel for dissemination of information" (Interstate Shellfish Sanitation Conference, 1982).

Another aspect of United States shellfish regulation concerns shellfish of foreign origin. Such shellfish are not under the direct scope of this study, but require mentioning.

The importation of fresh or frozen shellfish are subject to the provisions of the Federal Food, Drug, and Cosmetic Act (and if in consumer size packaging, to the Fair Packaging and Labeling Act) and to additional controls under the National Shellfish Sanitation Program.

As the basis of the National Shellfish Sanitation Program is to assure safe shellfish through stringent application of sanitary controls at the source, importation

of shellfish under this program poses some problems. For example, in the absence of known growing water quality, an objective analysis is not adequate to assure the safety of imported shellfish. In addition, there are no practicable, analytical procedures for detecting the broad spectrum of potentially harmful contaminants and naturally occurring marine biotoxins common to shellfish worldwide. Further, it is recognized that shellfish analyses alone are neither reliable nor indicative of the unsampled portion's quality. Thus, to assure the quality of imported shellfish and avoid outbreaks of illness, additional national Shellfish Sanitation Program controls are used and those foreign countries that satisfactorily apply these controls are entitled to certify shellfish products.

For a foreign country to become a National Shellfish Sanitation Program participant, an official agency of that country agrees to the general terms of the Program through the means of a memorandum of understanding with the Food and Drug Administration. The countries currently having effective memoranda of understanding are Australia, Canada, England, Iceland, Japan, Korea, Mexico, and New Zealand.

A country wishing to negotiate a shellfish memorandum of understanding must supply to the Food and Drug Administration evidence that demonstrates that the government has laws, rules, and regulations equivalent to those required under the Manuals of Operation. Also, the

government should have the resources necessary (trained personnel, laboratory facilities, etc.) to provide controls over the country's export shellfish industry.

Once a country has an effective memorandum of understanding, its shellfish control authority may submit certificates of their certified shellfish shippers to the Food and Drug Administration. The Food and Drug Administration in turn, publishes all the certified shippers in the Interstate Certified Shellfish Shippers List.

Summary

The history and background of United States food regulation and shellfish regulation, in particular, are outlined. The method of operation of the Interstate Shellfish Sanitation Conference is also given. Imported shellfish and problems related to their control are also mentioned.

CHAPTER IV

RESEARCH METHOD AND DATA COLLECTION

Method of Research

A survey is the method of research used. The study is based on an investigation into the use of differing operational and intergovernmental practices by State shellfish sanitation programs in maintaining safe, marketable shellfish, as well as environmentally healthy growing areas and harvest grounds.

Instrument of the Study

The primary method of inquiry is a questionnaire presented to key State shellfish regulatory officials (see Appendix 6). The questionnaire is divided into four major categories:

- I. Organization and Policy
- II. Intergovernmental Program Activities
- III. Operations
- IV. Program Activities & Functions

The questionnaire is directed to aspects of the State shellfish sanitation programs, which are determinants of safety. Particularly of interest are 1) the operational

aspects of water quality surveys, 2) growing area classification and patrol, and 3) intergovernmental activities. Effective management of these areas is crucial in achieving shellfish of safe quality and maintaining that the consumer is protected from harmful shellfish.

Insights into the operation and management of the State shellfish programs is important for an understanding of the present status of shellfish control and a necessity for future program planning.

Description of Research Population

The population under study is the State Shellfish Sanitation Programs of the 23 shellfish-producing states in the United States. These states are participants in the Interstate Shellfish Sanitation Conference.

Research Procedure

Questionnaire Development

Research indicated that states are responsible for five major functional duties in the management of their state programs:

- 1) survey of growing areas
- 2) plant inspections
- 3) patrol activities
- 4) laboratory analysis
- 5) resource management.

The focus is on the intergovernmental and operational practices utilized in performing the above functions, as other studies have been conducted concerning the technical aspects and problems facing the shellfish industry (National Shellfish Sanitation Workshop Proceedings, 1971, 1974; National Marine Fisheries Service, 1977; Hunt, 1979; Dressel et al., 1983; Tuttle, 1985).

To gather this information, questions were needed which addressed agency responsibility, resource allocation, and management techniques. Questions of resource allocation and funding, however, were omitted on the advice of federal shellfish officials. Such information, though known by state shellfish regulatory officials, is not always readily accessible to them. A lengthened response time by state officials to the questionnaire was assumed to result. States have also been reluctant to supply such information on past federal surveys. For these reasons it was suggested that resource allocation and funding questions be omitted, as they would perhaps contribute to a diminished number of responses or delays in response time.

The questionnaire was designed to accomplish the objectives based on the above specified five functional areas. Categories I and III, Organization and Policy, and Operations, respectively, were designed to answer questions of agency responsibility. Categories II and IV, Intergovernmental Program Activities, and Program

Activities and Functions, respectively, were designed to answer questions concerning management techniques.

Questions were designed to be clear, concise, and readily answerable. To further facilitate receiving as many responses as possible, a summary of responses was offered to those respondents who wished to receive the results of the survey. Questionnaires were sent to key state shellfish regulatory officials in charge of growing areas. These officials were selected based on their access to information of their state's overall shellfish operations.

During the development of the questionnaire, great interest in the study was expressed by the Food and Drug Administration and the National Oceanic and Atmospheric Administration. The Food and Drug Administration's interest stemmed from their concern about the role of the states in the Interstate Shellfish Sanitation Conference. The study also parallels the Food and Drug Administration's role in the Interstate Shellfish Sanitation Conference of evaluation of state programs.

The interest expressed by the National Oceanic and Atmospheric Administration focused on the intergovernmental aspect. Prior studies conducted by them were similar, but focused more on technical aspects. The present study could add information to their data base by contributing a deeper insight of the State role under the Interstate Shellfish

Sanitation Conference in respect to state intergovernmental activities.

Pilot Test

A pilot test of the questionnaire was conducted prior to the mailing of the survey itself. Input was solicited from state as well as federal shellfish regulatory officials. Feedback for the pilot test was directed primarily to the expected willingness of state officials to respond at all, to respond in a timely fashion, or to respond accurately to the inquiry about the management of their state programs. Further comments on content, structure, and length were also invited.

Federal shellfish regulatory officials were from the Food and Drug Administration and the National Oceanic and Atmospheric Administration. Two state shellfish regulatory officials were chosen from North Carolina and South Carolina.

A copy of the questionnaire was mailed to both sets of officials. State officials responded by mail, while federal officials responded by phone. Responses to the pilot test indicated the need for minor structural and content changes. Also mentioned was the likelihood of state response. It should be noted that the Interstate Shellfish Sanitation Conference and the National Oceanic and Atmospheric Administration were conducting studies of state shellfish programs (also utilizing questionnaires) in the same time

frame of this study. Response from federal officials suggested that such a coincidence could lead to a diminished number of responses.

A copy of the cover letter, title page to the questionnaire, the questionnaire, and a list of the key state regulatory officials to whom questionnaires were sent can be seen in Appendix 6.

Distribution and Follow-up

Ten of the twenty-three states contacted responded to the initial mailing of the questionnaire. Of these ten, three returned additional information on their state's current policies and regulations for managing shellfish resources. The additional information included copies of state statutes and program guidelines.

One month after the initial mailing, reminder notes, along with an additional copy of the questionnaire, were sent to delinquent responders. From this follow-up effort, eight additional responses were obtained, for a total of 18 responses from the pool of 23 questionnaires distributed. Of these eight, three returned additional information on their state's current policies and regulations for managing shellfish resources. The additional information included memoranda from agency to industry, management plan criteria for growing water reopenings, growing area surveys, and a summary of bacteriology laboratory sampling. Additionally, four of the 18 states responding included information on

agency responsibility and the organizational structure of their state's shellfish programs. A copy of the follow-up note can be seen in Appendix 6.

Data Processing

Results of the survey are tabulated and presented in the following chapter. Approximately 78% of those surveyed responded. Results of each question are given, followed by a discussion of each response individually, where needed. This is followed by a general discussion of all responses and a summary.

Summary

The method of research and data collection for the study are outlined. The instrument of the study, the research population, and the research procedure is given in detail.

CHAPTER V
RESULTS OF THE SURVEY

Do you wish to receive a summary of information submitted by all of the states responding to this questionnaire?

Yes 18
No 0

Send to: _____

I. ORGANIZATION AND POLICY

1. Do you have a division or agency which specifically regulates shellfish? (Check appropriate response)

Yes 18 No 0

All states responding had existing shellfish programs.

2. What specific activities or functions is each division/agency responsible for?

<u>Function</u>	<u>Division/Agency</u>
Survey of Growing Areas	_____
Plant Inspections	_____
Patrol Activities	_____
Laboratory Analysis	_____
Resource Management	_____
(relaying)	_____

Responses indicate that current agency responsibility for state shellfish programs lies within specific divisions of State Departments of Health or of Environmental Control/Natural Resources. Within these divisions, the hierarchy of responsibility is further divided to extend responsibility to the level of Bureau/Branch or Section.

Eleven states who responded share responsibility for the above functions between either of the two departments stated above. Six states who responded have general responsibility for their shellfish programs only within one department (either their departments of Health, as with 3 of these 6 states; or with their departments of Environmental Control/Natural Resources, as with the other 3 states). In the

remaining state, responsibility for the management of health and environmental concerns lies within one department.

It should also be noted that eight of the responding states share responsibility for patrol activities with law enforcement departments or divisions in their state. In one case, this responsibility has legally been given to local communities. Likewise, one state shares laboratory duties with local and county labs.

Actual responsibility, in terms of implementing duties on a daily basis, for the specific functions listed above, lie at the Bureau/Branch or Section organizational level of hierarchy, particularly in regional offices. A model state organizational chart to illustrate the different levels of hierarchy discovered can be seen in Figure 1.

3. What is the total number of full-time staff employed within the division/agency who are responsible for the management of shellfish?

Responses to this question range from 3/4 of a position to 279. It was noted in some instances that full-time staff have other duties besides shellfish and, as such, only devote part of their time to shellfish.

- 3a. Of this number, how many full-time staff carry out the following regulatory duties and responsibilities in managing shellfish in your state?

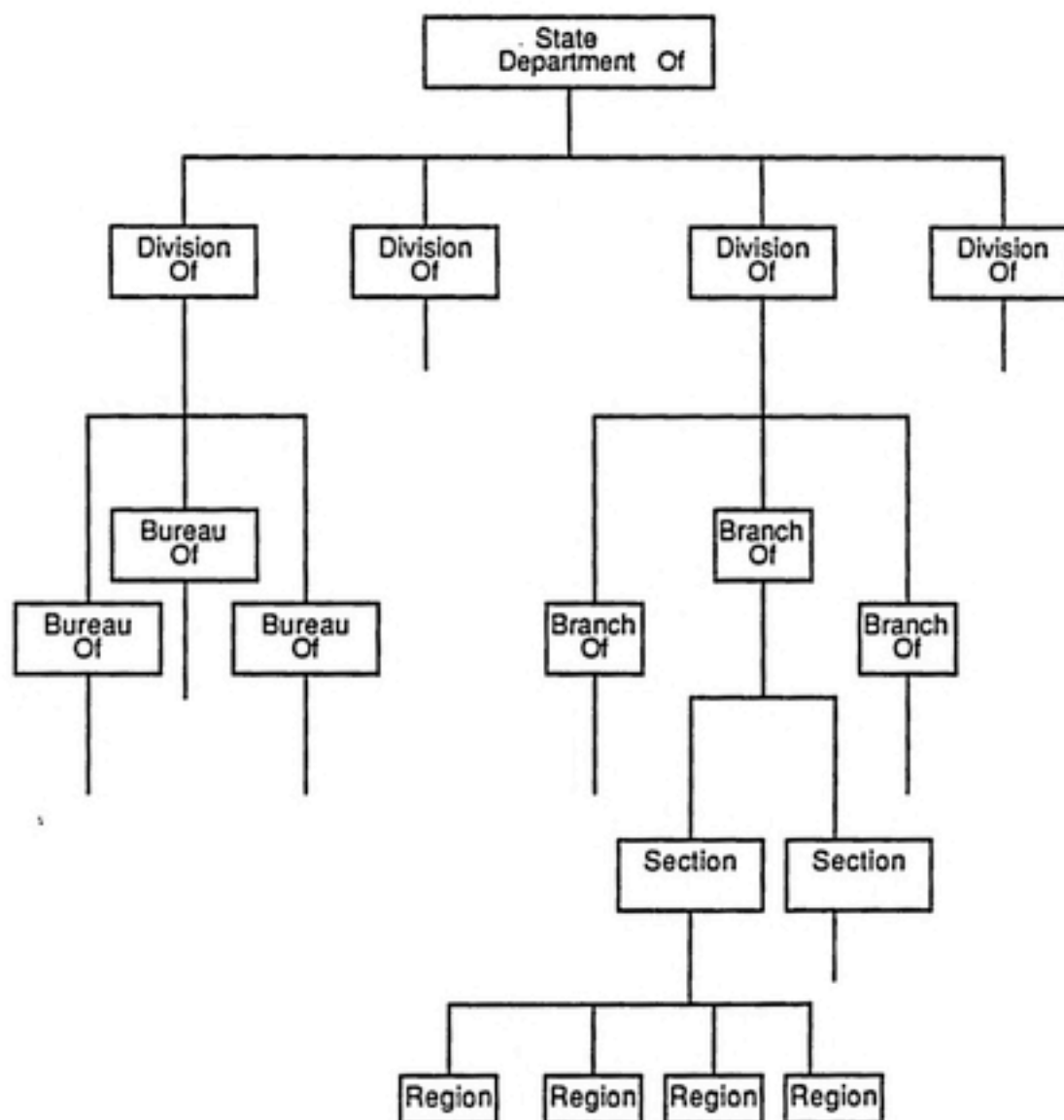
Growing Area Surveys	_____
Plant Inspections	_____
Patrol Activities	_____
Laboratory Analysis	_____
Resource Management	_____

For tabulation purposes, states have been divided into three categories based solely on the number of shellfish staff indicated in response to the above question. This categorization should in no way be related to the amount of a state's production of shellfish or the subsequent market values of this shellfish. The three categories and their criteria are:

- 1) Minor Shellfish States - Zero to ten state personnel responsible for shellfish management.
- 2) Median Shellfish States - Eleven to fifty state personnel responsible for shellfish management.

FIGURE 1.

MODEL STATE ORGANIZATION CHART



3) Major Shellfish States - Greater than fifty state personnel responsible for shellfish management.

Seven states who responded can be classified as minor shellfish states. Responses range from 3/4 of a position to ten. In this category it should be noted that number of full-time staff is no way reflective of shellfish agency size. Likewise, the capability of shellfish management in these states should not be diminished. Three states have one person responsible on a full-time basis. Obviously duties in any of the five categories must be shared. A more accurate account, in the case of such small numbers, includes looking at the number of agency staff in terms of person-years.

Nine states who responded can be classified as median shellfish states. Their range of responses was from 11-43 full-time staff.

Two states who responded can be classified as major shellfish states. Responses of 182 and 279 full-time staff for shellfish regulatory duties was given.

II. INTERGOVERNMENTAL PROGRAM ACTIVITIES

1. Indicate frequency of contact your state has with the following federal agencies regarding shellfish management. (Please indicate with corresponding number.)

very frequent	frequent	infrequent	rare	none
1	2	3	4	5
Food & Drug Administration (FDA)				
National Marine Fisheries Service (NMFS)				
National Oceanic & Atmospheric Administration (NOAA)				

Responses indicate that all states responding have some degree of contact with the Food and Drug Administration. Agency contact with the National Oceanic and Atmospheric Administration, in general, and its National Marine Fisheries Service, in particular, however, are infrequent or rare. The responses obtained can be expressed in the following percentages, based on responses of frequent and very frequent contact: contact with the Food and Drug Administration - 94%; contact with the National Marine Fisheries Service - 22%; and contact with the National Oceanic and Atmospheric Administration - 17%. A synopsis of the results can be seen in Figures 2-4.

FIGURE 2.
FREQUENCY OF STATE CONTACT WITH THE
FOOD AND DRUG ADMINISTRATION

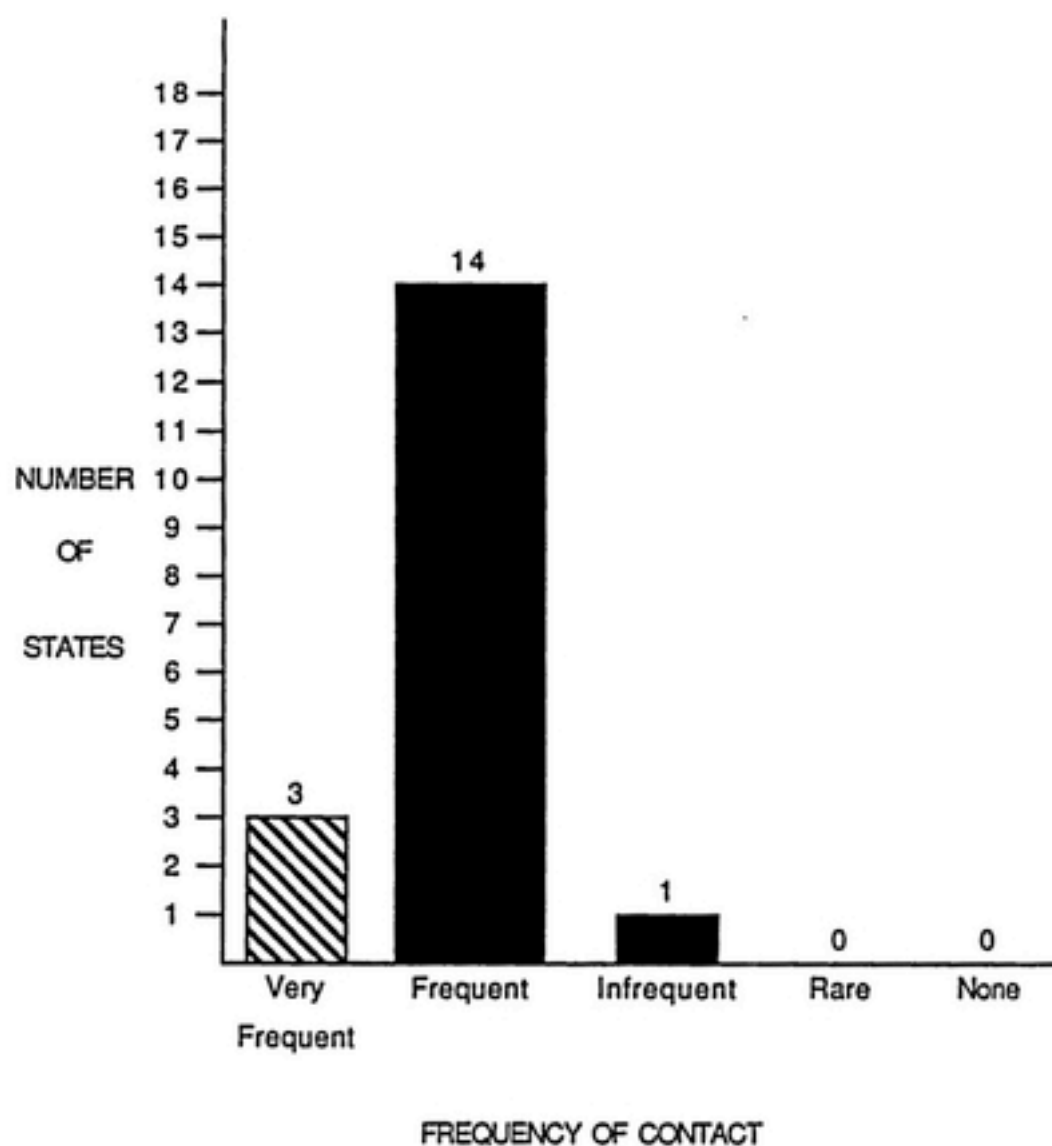


FIGURE 3.

FREQUENCY OF STATE CONTACT WITH THE
NATIONAL MARINE FISHERIES SERVICE

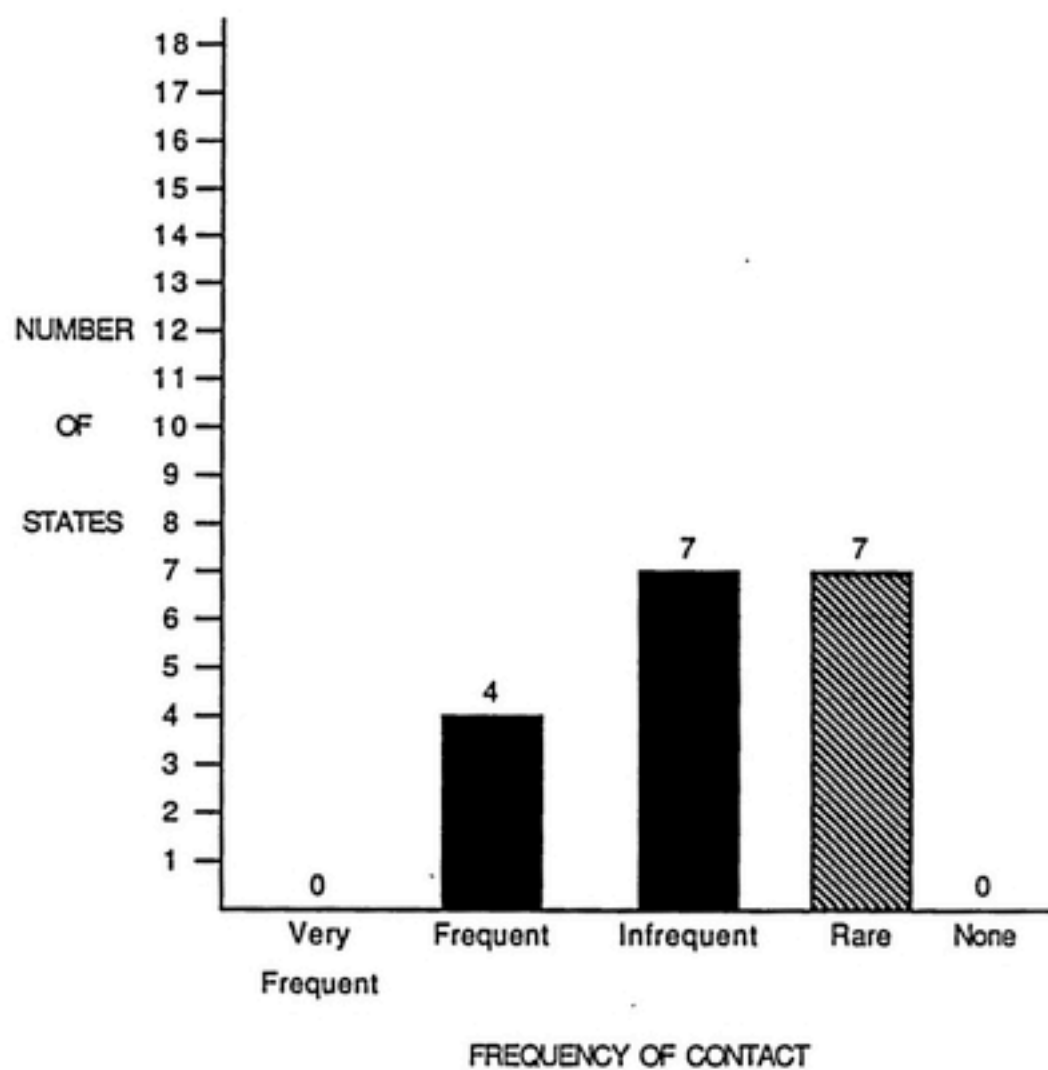
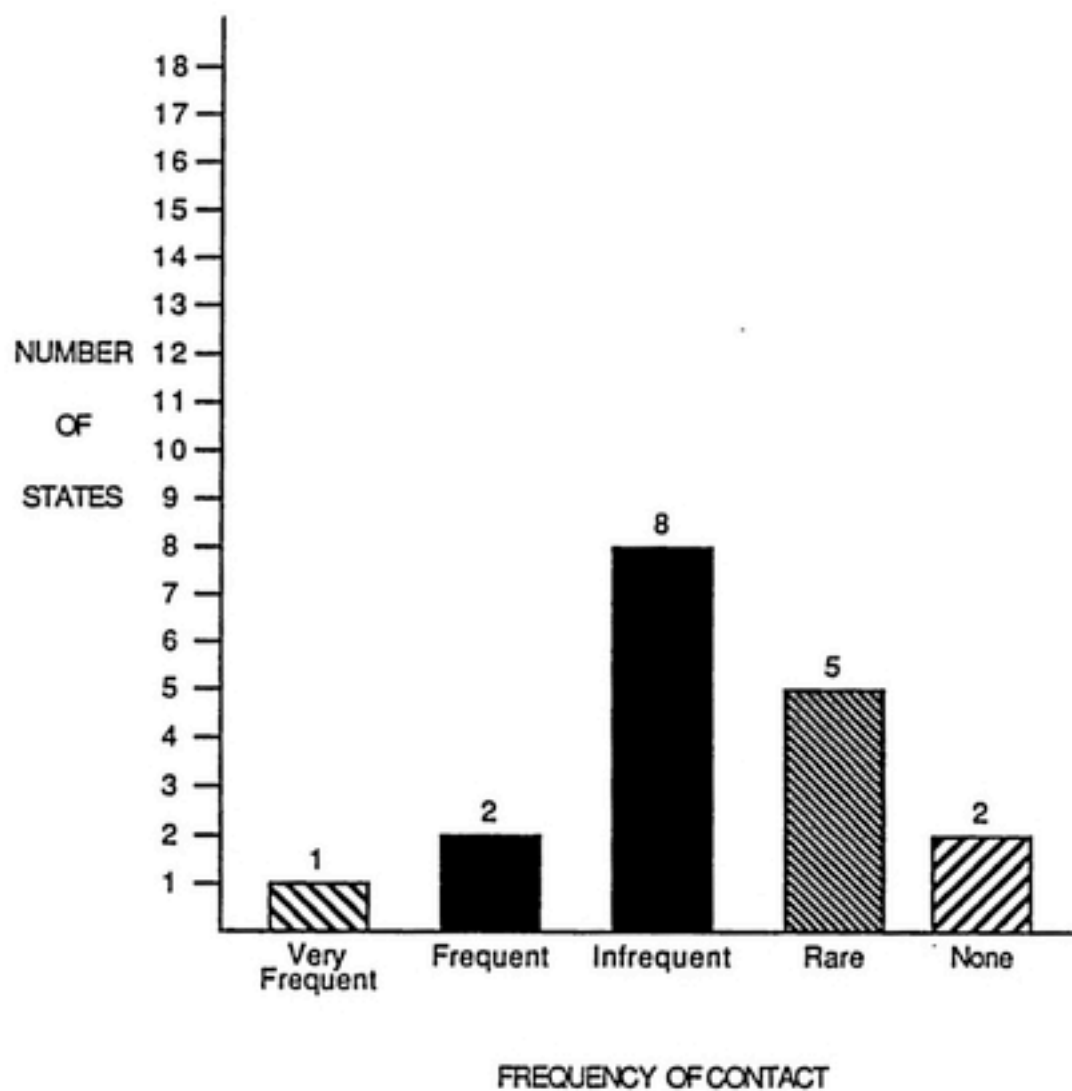


FIGURE 4.

FREQUENCY OF STATE CONTACT WITH THE
NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION



Discussion: Frequency of contact is important because the sharing of information can facilitate a more coordinated federal, state, and industry program.

Frequency of contact with the federal agency specified is loosely defined, here referring to contact on a basis of approximately less than or equal to once a month and up to quarterly contact.

Based on the responsibilities of each agency toward shellfish resources, the responses were both expected and surprising. It was expected that Food and Drug Administration contact would be high, as this agency has the responsibility for the evaluation of State shellfish programs. On the other hand, since the National Oceanic and Atmospheric Administration, in respect to shellfish, is responsible for assisting the States in managing, using, and conserving resources in the coastal zone, a frequency of contact greater than 17% was expected. Authority for these actions is given to the National Oceanic and Atmospheric Administration in the Coastal Zone Management Act of 1972.

Response to contact with the National Marine Fisheries Service was not as surprising. This agency has the responsibility toward shellfish resources of managing, conserving, developing, and protecting living marine resources which depend upon healthy and productive marine habitats. Response was not as surprising with this agency because its authority under the Magnuson Fishery and Conservation Act of 1976 is for federal waters three to two hundred miles out to sea. State waters, where shellfish resources are primarily found, are still under the authorization of the States.

2. Is your state currently involved, or has it been involved within the past 2 to 5 years, in interstate activities that would have an impact on shellfish growing waters (i.e., the Chesapeake Bay Agreement of 1983)?

Yes	5
Currently involved	5
Past 2-5 years	2
No	5
Not Applicable	8
(for states who do not share an estuary containing shellfish resources)	

If Yes, please refer to the following:

2a. Which states are involved?

The states currently involved in interstate agreements have these agreements with at least one, and up to four other states involved. On the average, agreements currently undertaken involve four states sharing responsibilities.

2b. Are the interstate activities undertaken by your state guided by written Memoranda of Understanding (MOUs), nonformalized agreement, legal agreement, or other?

MOUs	<u>1</u>
Nonformalized Agreement	<u>4</u>
Legal Agreement	<u>2</u>
Other	<u>2</u>

(please indicate)

- 1) National Shellfish Sanitation Program and Interstate Shellfish Sanitation Program cooperative agreement and
- 2) Joint ventures based on geography, concerning value and clean-up.

If No, please refer to the following?

2c. Is your state planning to become involved in interstate efforts within the next 1-2 years?

Yes 0 No 4 Don't Know 1

2d. Which of the following have you encountered as obstacles to forming interstate agreements?

Unwilling Neighboring States	<u>0</u>
Home State Unwilling	<u>0</u>
Geographical Location of Home State	<u>0</u>
Lack of Communication Channels	
with Neighboring States	<u>0</u>
Other (please indicate)	<u>4</u>
1) State agency has not pursued interstate agreements;	
2) Lack of need;	
3) Shared estuaries are unclassified (unsurveyed; unapproved); and	
4) The question has not come up	

3. Check the following strategies which your state alone (nonregional efforts) has undertaken in the last 2 to 5 years to improve or safeguard shellfish.

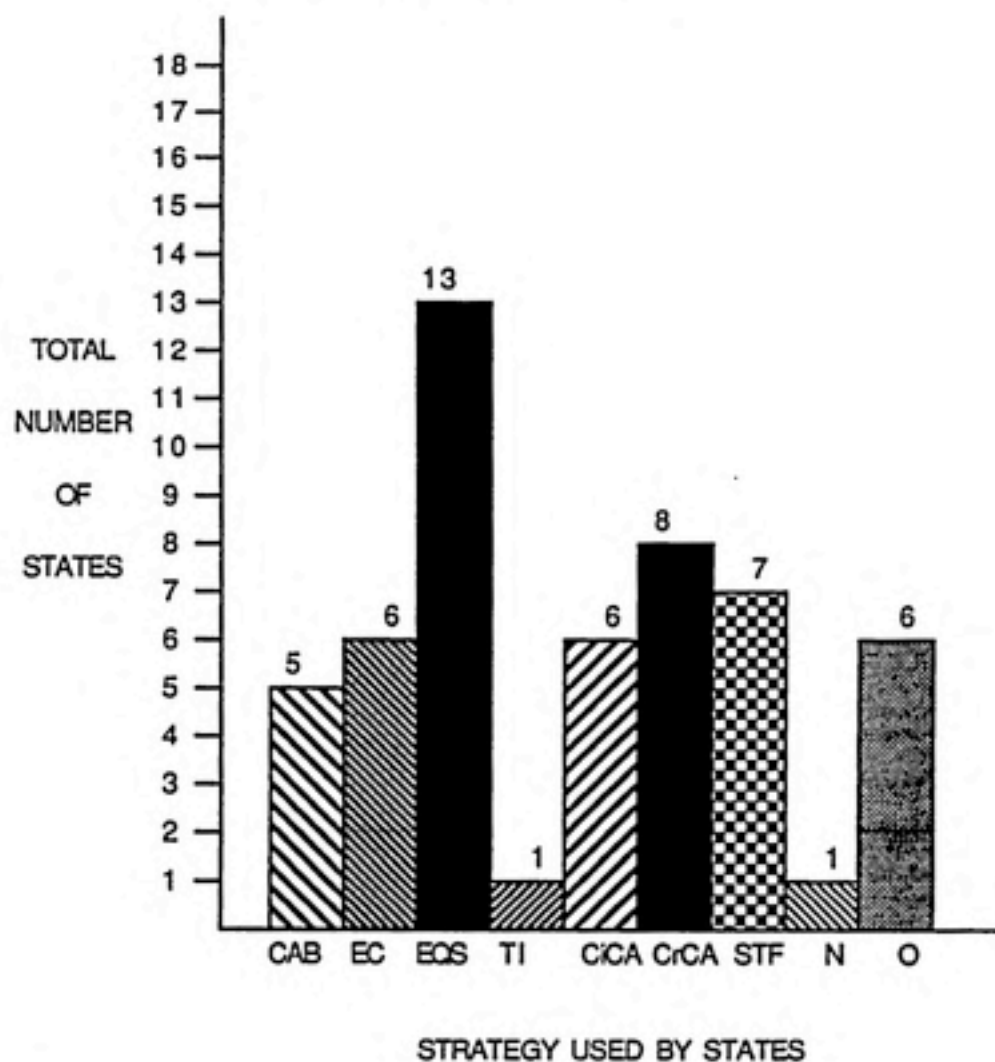
Citizen Advisory Board (CAB)	5
Enforcement Conferences (EC)	6
Environmental Quality Standards (EQS)	13
Tax Incentives (TI)	1
Civil Court Action (CiCA)	6
Criminal Court Action (CrCA)	8
Shellfish Task Force (STF)	7
None (N)	1
Other (please list) (O)	6
1) Establishment of a lot sampling program for approved growing areas.	
2) Modernization of the state's shellfish program through increased technical capabilities;	
3) Creation of a water quality authority to enhance and protect growing areas;	
4) Review of NPDES applications and regulatory permit review; and	
5) Creation of a joint action group - A cooperative venture between legislature, citizens, seafood dealers, and harvesters to propose legislation.	
6A) Legislative action to ban overboard discharges;	
6B) Training program for municipal shellfish conservation officers.	

The total number of states which used each strategy can be seen in Figure 5. It should be noted that not all states used all categories. The range of strategies used per state is from 0-5 strategies. The following distribution was observed:

<u>Number of Strategies Used per State</u>	<u>Number of States</u>
0	1
1	5
2	5
3	1
4	3
5	3

The use of strategies per state can be seen in Figure 6.

FIGURE 5.
STATE USAGE OF STRATEGIES



LEGEND:

CAB - Citizen Advisory Board

EC - Environmental Conferences

EQS - Environmental Quality Standards

TI - Tax Incentives

CiCA - Civil Court Action

CrCA - Criminal Court Action

STF - Shellfish Task Force

N - None

O - Other

FIGURE 6.
USE OF STRATEGIES PER STATE

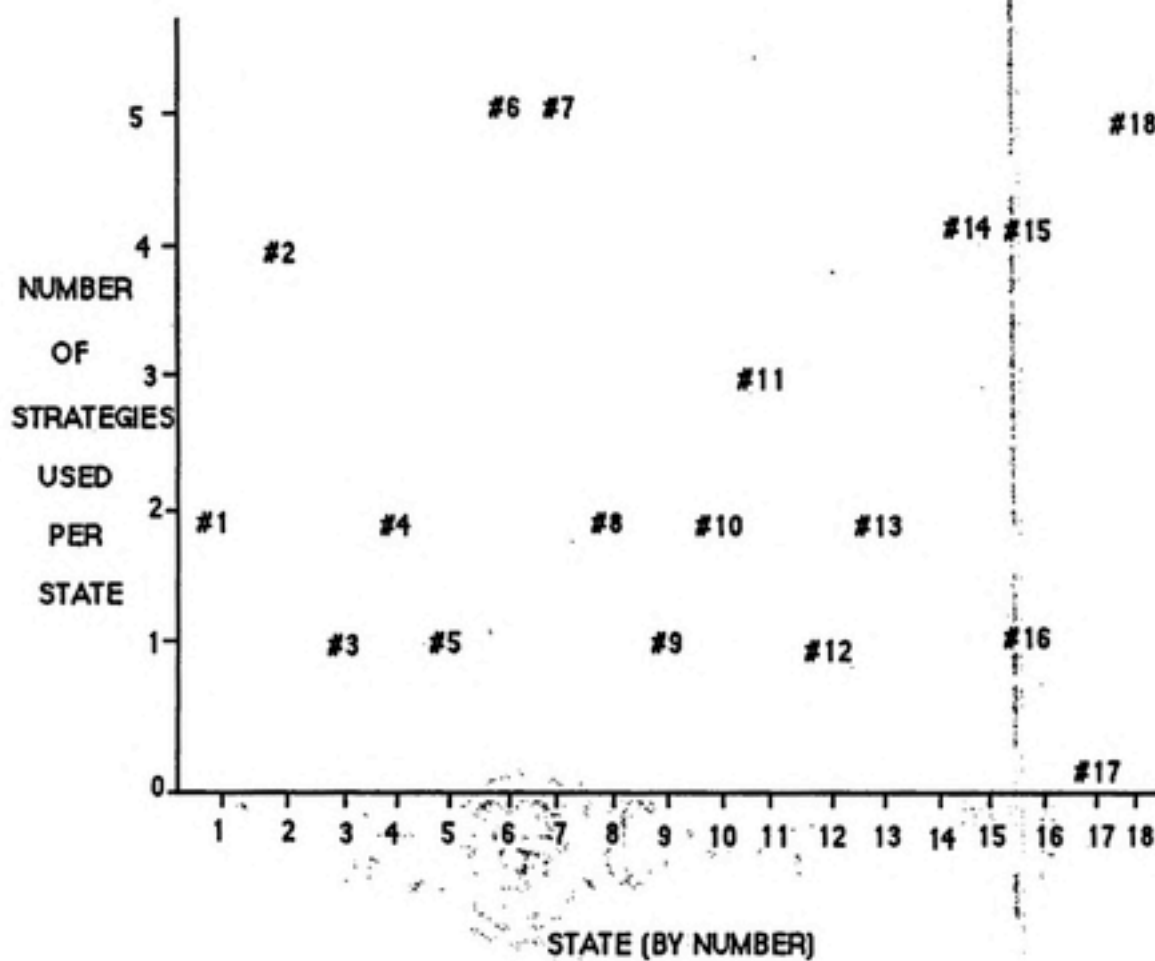


TABLE 1. STRATEGY EFFECTIVENESS

STRATEGY	DEGREE OF EFFECTIVENESS					
	VE	E	N	INE	VINE	DK
Citizen Advisory Board		4		1		
Environmental Conferences	1	3	2			
Environmental Quality Standards	1	10	2			
Tax Incentives						1
Civil Court Action		5		1		
Criminal Court Action	2	3	2	1~		
Shellfish Task Force	1	4	2			
Other^					1	

LEGEND:

VE : Very Effective

E : Effective

N : Neutral

INE : Ineffective

VINE : Very Ineffective

DK : Don't Know

~ Due To Low Fines

^ Refers to Joint Action Group

NOTE : NUMBERS CORRESPOND TO NUMBER OF STATES RESPONDING

Administrative/Operating Constraints

- 1) Insufficient resources (funding, staff, & labs)
- 2) Long geographical distances to growing areas
- 3) Harvest on public ground
- 4) Nonpoint source pollution
- 5) Lack of good shellfish growing areas
- 6) Importation of questionable quality shellfish from certified/non-certified interstate shippers
- 7) State shellfish industry financially inconsequential
- 8) Lack of industry cooperation/support
- 9) Reclaiming closed areas due to pollution

Legal Constraints

- 1) Lack of clear regulations
- 2) Low fines for prohibited violations
- 3) Lack of adequate control of animal and boat pollution
- 4) Low priority of shellfish as related to other issues
- 5) Limited natural resources on private and military land

Technical/Analytical Constraints

- 1) Lack of a truly representative bacteriological indicator
- 2) Major deficiencies in NSSP Manual (1986) (criteria outdated and generally not scientifically supported)

Public Constraints

- 1) Lack of knowledge about shellfish concerns on part of industry and general public
- 2) Coastal development and competing user groups
- 3) Too many harvesters for amount of resource
- 4) Too many landing areas
- 5) Industry and public doubt about growing water examination methods

6. What are the major factors contributing to your state developing shellfish programs? (Check all that apply.)

Environmental Deterioration	<u>10</u>
Concern for the Public's Health	<u>18</u>
Federal/Industrial Financial Incentives	<u>2</u>
State Requirements and Mandates	<u>15</u>
Other (please indicate)	<u>3</u>
1) Need to comply with the cooperative efforts of the Food and Drug Administration in the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference;	

- 2) Commitment by the shellfish industry; and
- 3) Interest in resource enhancement

7. Do you think a stronger or different state role is needed in managing shellfish? Or both?

Stronger role:	Yes	<u>6</u>	No	<u>8</u>
Different role:	Yes	<u>0</u>	No	<u>9</u>
Both:	Yes	<u>1</u>	No	<u>7</u>

7a. If you answered yes to any of the above, in what way should the role be altered?

Eight responses to this question were given. Four of these indicated that a stronger state role could best be facilitated through an increase in funding and/or staff. Other responses for a stronger state role were as follows:

One indicated that fines for illegal harvesting should be strengthened. One stressed that the state agency must be responsive to the needs of the shellfish industry. Another stated that shellfish harvesting area closures should serve as red flags to state environmental monitoring and permitting agencies. Lastly, one state indicated that current state efforts are thought to be sufficient.

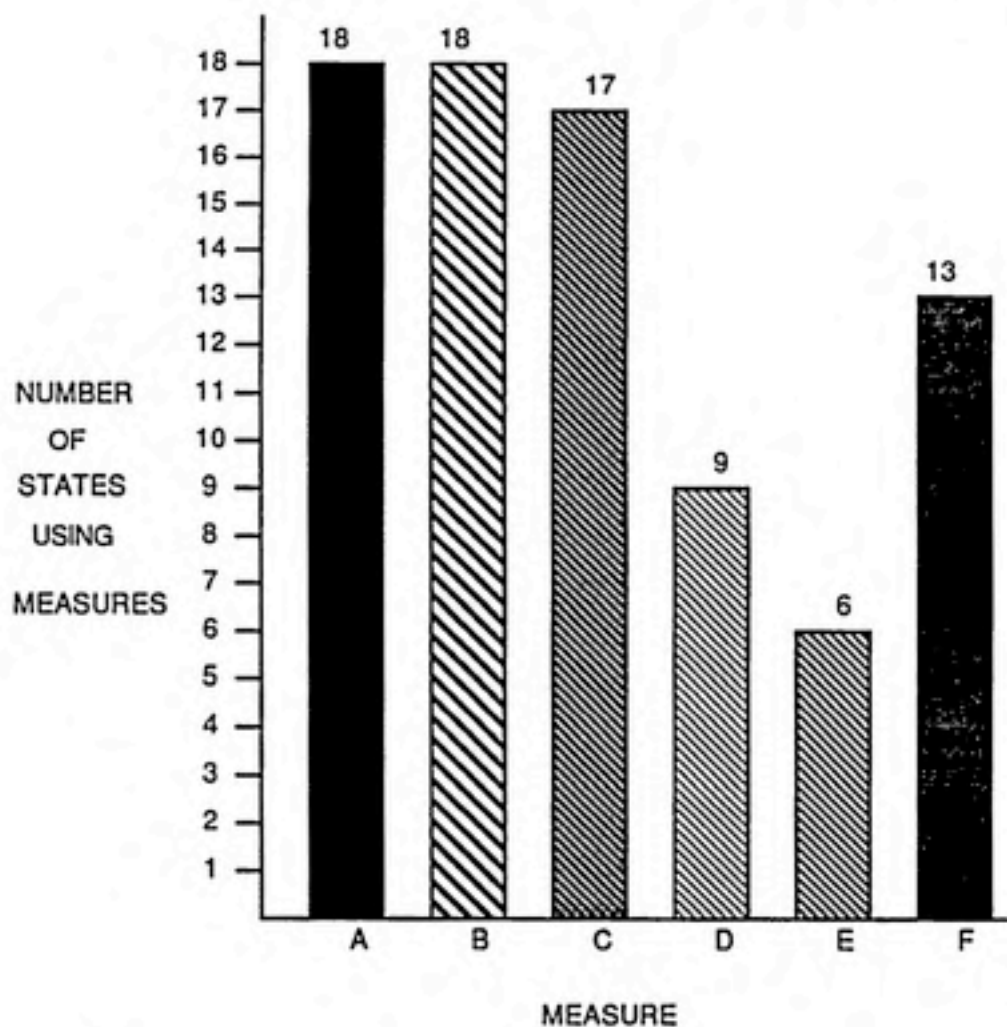
III. OPERATIONS

1. Of the following, what are the measures on which your state bases its classification of waters? (Check all that apply.)

MEASURE		
A	Water Quality Studies	<u>18</u>
B	Pollution Source Survey	<u>18</u>
C	Hydrographic & Meteorological Characteristics	<u>17</u>
D	Harvesting Practices	<u>9</u>
E	Resources (specific species abundance & distribution)	<u>6</u>
F	Interrelationships of the foregoing factors	<u>13</u>
G	Other (please indicate)	<u>0</u>

A summary of the above responses is given in Figure 7.

FIGURE 7.
STATE USAGE OF WATER CLASSIFICATION MEASURES



LEGEND:

- MEASURE A - Water Quality Studies
- MEASURE B - Pollution Source Survey
- MEASURE C - Hydrographic & Meteorological Characteristics
- MEASURE D - Harvesting Practices (Commercial, Sport,
Wet storage facilities, Landings, Active leases)
- MEASURE E - Resources (specific species abundance & distribution)
- MEASURE F - Interrelationships of the Foregoing Factors

2. What is the total area (in acres) of classified shellfishing waters within your state?

The range of classified shellfishing waters was from 1-2,263,000 acres.

- 2a. How much of this area (in acres) is within your division or agency's jurisdiction?

All states responding were responsible for 100% of the area stipulated.

3. How many acres are prohibited? _____ Approved? _____
 Conditionally approved? _____ Restricted? _____
 Non-productive? _____ Other classifications? _____
 (Please indicate classification)

Classifications of state shellfishing waters by state can be seen in Table 2. The classifications are given for all twenty-three of the shellfish-producing states. Several other classifications are used by states. These include: Unclassified (unapproved) instead of Nonproductive, seasonally condemned, seasonally condemned around marinas, polluted instead of Restricted, and conditionally restricted.

Discussion: This question answers the broad question of, "What do we know?" Updates on this information lend themselves to studies of trends in classification and of information relating improving or declining State water quality. With such information, a focus and direction for future planning can be established, improvements begun, and problems diffused. Thus, to obtain an overall picture of the current status of US shellfishing waters, information for all 23 states is included. States are listed according to the Interstate Shellfish Sanitation Conference regions. This information is accessible to the public and is found in the 1985 National Estuarine Register.

IV. PROGRAM ACTIVITIES AND FUNCTIONS

The National Shellfish Sanitation Program Manual of Operations states five functions for states to perform in the management of shellfish:

1. Shoreline Surveys/ Water Quality Sampling
2. Inspection of packing/processing plants
3. Laboratory Analysis
4. Enforcement Activities
5. Resource Management.

TABLE 2.

CLASSIFICATIONS OF STATE SHELLFISHING WATERS BY STATE

Region & State	Approved	Prohibited	Conditionally Approved	Restricted	Non-Productive	Other	Total
Region 1							
MA.	255,000	41,000	1,000	5,000	500,000		802,000
ME.	36,500	8,800	16,100	2,500	?		60,000+
NH.	4,000	6,000	0	0	0		10,000
RI.	62,025	18,602	11,447	—	—		92,074
Region 2							
CT.	309,000	77,714	5,654	0			392,419
NJ.	483,903	114,077	19,375	43,205			~600,000
NY.	900,000	200,000	Varies	Varies	?		1,100,000
Region 3							
DE.	209,000	19,000	3,000	0	44,000		275,000
MD.	~1,053,000	0	0	~50,000	~90,000		~1,200,000
VA.	—	?	2,354	91,186	91,439	4,473	500,000

NOTE : NUMBERS GIVEN ARE IN ACRES

REGIONS REFER TO INTERSTATE SHELLFISH SANITATION
CONFERENCE REGIONS

CONTINUED ...

TABLE 2. CONTINUED

Region & State	Approved	Prohibited	Conditionally Approved	Restricted	Non-Productive	Other	Total
Region 4							
FL.	306,000	299,000	470,000	43,000	1,133,000	12,000	2,263,000
GA.	61,000	144,000	0	0	0		205,000
N.C.	1,716,642	316,232	—	—			2,100,000
S.C.	224,139	11,530	9,140	60,621	N/A		305,430
Region 5							
AL.	73,919	102,656	194,548	0	2,468		373,591
LA.	0	31,000	3,462,000	0	0		3,493,000
MISS.	123,000	96,000	171,000	0	0		390,000
TX.	1,204,850	N/A	N/A	SEE OTHER	N/A	315,540	1,520,390
Region 6							
AL.	8,158	0	0	0	0		8,158
CA.	11,990	—	3,682	48	—		15,720
HI.		1					1
OR.	14,470	9,710	11,601	N/A	N/A		35,781
WA.	150,000	20,000	45,000	30,000	>1,000,000		250,000

NOTE: NUMBERS GIVEN ARE IN ACRES

REGIONS REFER TO INTERSTATE SHELLFISH SANITATION
CONFERENCE REGIONS

The following questions pertain to activities involved in each function.

Shoreline Surveys/Water Quality Sampling

1. What method is used in conducting shoreline surveys within your state?

Desktop 4 Field 18

2. Approximately what percentage of your state's classified shellfishing waters are surveyed annually?

The percent of classified shellfishing waters surveyed annually by states ranges from 0% to 100%. A summary of the percent of waters surveyed annually can be seen in Figure 8.

3. Check each of the following parameters which are included in the water quality monitoring program conducted by your division/agency.

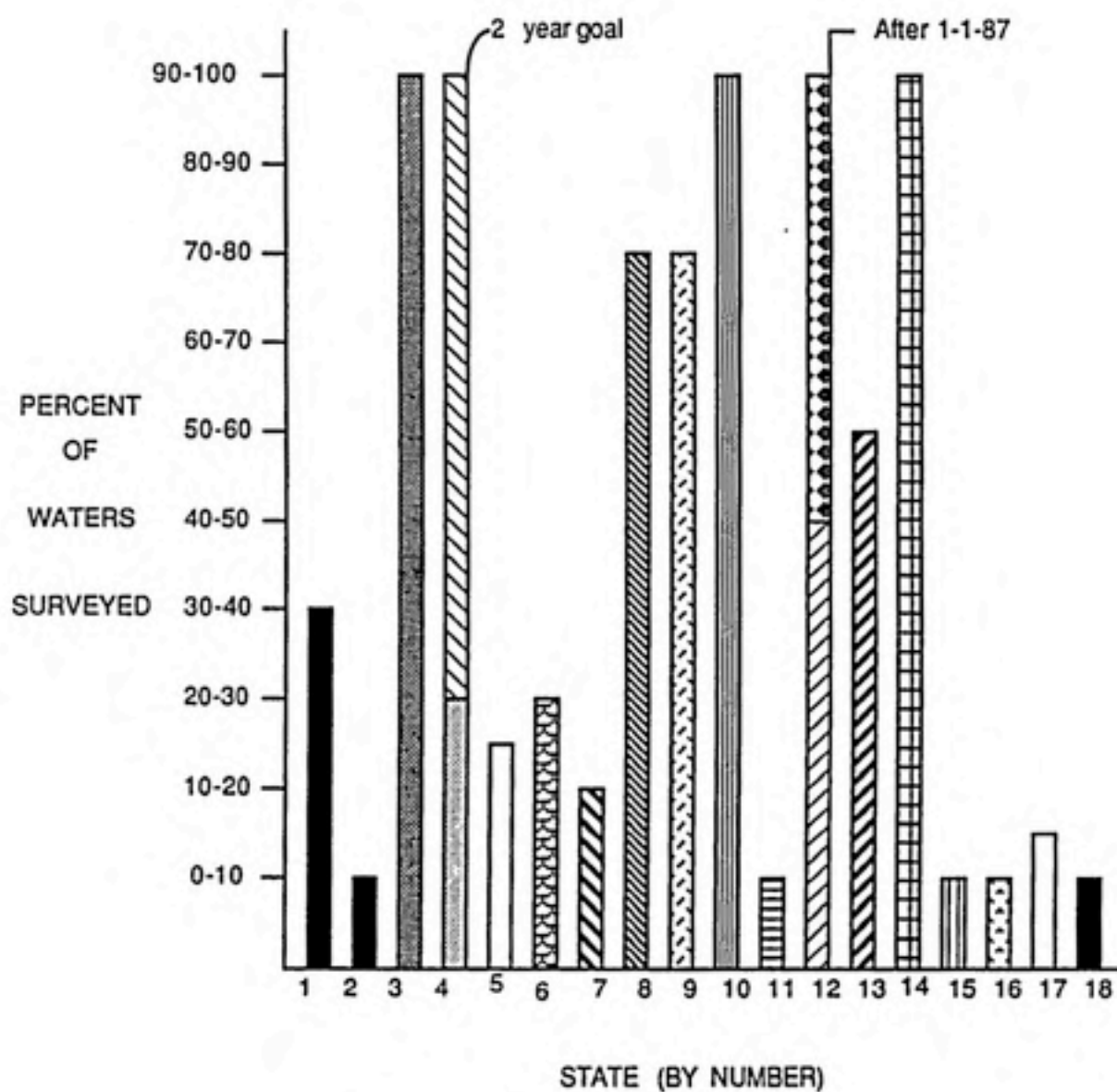
Fecal Coliform	<u>17</u>
Total Coliform	<u>11</u>
Viruses	<u>2</u>
Paralytic Shellfish Poisoning	<u>9</u>
Heavy Metals	<u>12</u>
Petroleum Hydrocarbons	<u>10</u>
Chlorinated Hydrocarbons	<u>9</u>
Other (please indicate)	<u>4</u>
1) Radiological; Organophosphates	
2) Salinity	
3) Special microbiological studies when required (fecal strep, IMViC)	
4) Fecal Strep, Enterococcus, Clostridium	

The number of parameters monitored per state ranges from one to seven or more:

<u>Number of Parameters Monitored per State</u>	<u>Number of States</u>
1	3
2	4
3	5
4	0
5	1
6	2
≥7	1

Discussion: Parameters monitored per state are listed according to the number of states that usually always include them in their surveys. Several states monitor some parameters (heavy metals, PSP, viruses, and the

FIGURE 8.
PERCENT OF WATERS SURVEYED, BY STATE



hydrocarbons) only occasionally, and some on a periodic basis. Heavy metals and the hydrocarbons are also monitored only in the meat samples of one state and if necessary or if indicated, in others. Results are summarized in Table 3.

Inspection of Packing/Processing Plants

1. What is the inspection frequency in your state?

Weekly	<u>0</u>	Semi-annually	<u>3</u>
Monthly	<u>11</u>	Annually	<u>12</u>
Quarterly	<u>4</u>	Other	<u>0</u>
(indicate frequency)			

One state indicated that the frequency of its inspections depends on the plant's operation. State plant inspection frequency is summarized in Figure 9.

Laboratory Analysis

1. Is growing water sampling and market sampling of shellfish meat conducted on a schedule?

Growing Water Sampling:

Yes 16 If yes, on what schedule? No 2

Schedule:

Weekly	<u>1</u>	Quarterly	<u>2</u>
Bi-monthly	<u>1</u>	Semi-annually	<u>0</u>
Monthly	<u>6</u>	Annually	<u>2</u>

Other responses indicate that growing water sampling is also conducted after pollution events or after periods of relaying and in one state, sampling varies from area to area.

Market Sampling:

Yes 13 If yes, on what schedule?

No 2

Schedule:

Weekly	<u>2</u>	Monthly	<u>6</u>
Bi-monthly	<u>1</u>	Quarterly	<u>2</u>
Occasionally	<u>1</u>		

One state indicated that their sampling schedule varies, depending on the plant.

TABLE 3.
DISTRIBUTION OF WATER QUALITY SAMPLING PARAMETERS

State	Coliform		Viruses	PSP	Heavy Metals	Hydrocarbons	
	Fecal	Total				Petroleum	Chlorinated
1	X				X		
2	X	X		X			
3	X						
4	X	X	X ^{''}	X ^{''}	X ^{''}	X ^{''}	X ^{''}
5	X						
6	X			X	X ^{''}	X ^{''}	X ^{''}
7	X	X			X	X	X
8	X	X		X	X	X	X
9	X	X		X	X ^{''}	X ^{''}	X ^{''}

CONTINUED ...

TABLE 3. CONTINUED

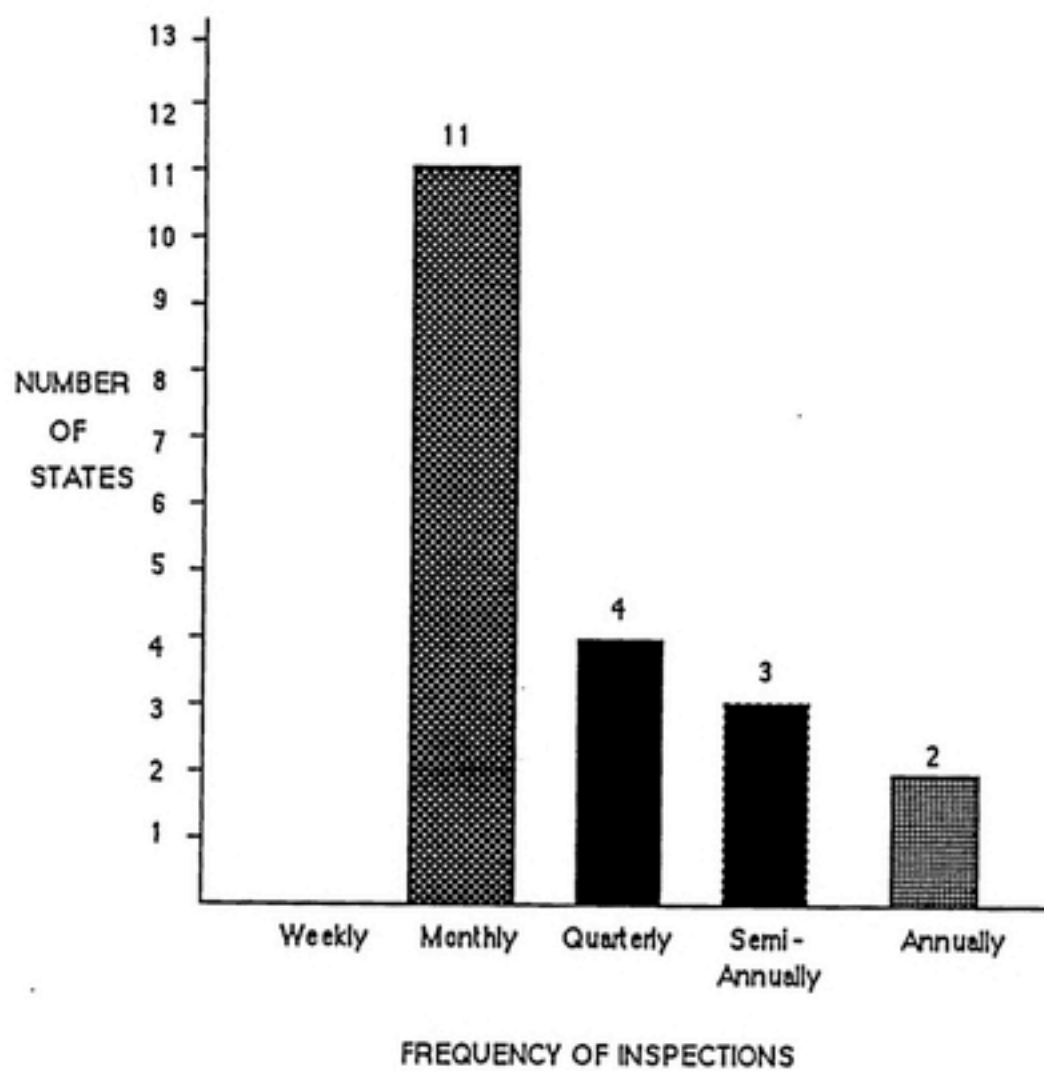
State	Coliform		Viruses	PSP	Heavy Metals	Hydrocarbons	
	Fecal	Total				Petroleum	Chlorinated
10	X	X		X	X	X	X
11	X			X	X**	X**	X**
12	X				X		
13	X	X	X"	X	X	X"	X
14	X	X					
15	X	X					
16		X		X*	X*	X*	X*
17	X				X	X	
18	X	X		X			

LEGEND: X": Occasionally or periodically
 X-: If necessary or indicated
 X*: For new areas
 X**: Shellfish meat only

PSP: Paralytic Shellfish Poison

FIGURE 9.

STATE PLANT INSPECTION FREQUENCY



2. Do lab personnel within your division/agency follow lab procedures as delineated in the NSSP Manual of Operations or modifications of such procedures?

Manual of Operations procedures	<u>17</u>
Modifications of procedures	<u>1</u>
No Answer	<u>1</u>

Enforcement Activities

1. How is harvesting controlled in your state? (Check all that apply)

Licensing & Permitting	<u>18</u>
Identifying Closed Areas	<u>16</u>
Patrol of Growing Areas	<u>18</u>
Other (indicate method)	<u>3</u>
1) Publication of Maps (2 states)	
2) Catch Reporting	
3) Publication of list of current closures	

Most states surveyed (16) control harvesting through the use of all three methods listed. Of these sixteen states, one additionally controls harvesting through the publication of maps. The remaining two states control harvesting through the use of two of the three methods listed - omitting the identification of closed areas. One of these two states, however, additionally controls harvesting through the use of catch reporting.

Resource Management

1. Who is responsible for the relaying of shellfish to another area for natural cleansing within your state? (Check all applicable)

State Patrol Agency	<u>13</u>
State Control Agency	<u>15</u>
Shellfish Industry	<u>8</u>

<u>Responsibility</u>	<u>Number of States</u>
All 3 responsible	7
Just Patrol Agency	1
Just Control Agency	3
Just Industry	1
Patrol & Control Agency	4
Control Agency & Industry	1

One state indicated that relaying is not done in their state.

Depuration

1. Does your state allow depuration?

Yes 12 No 6

If Yes, please refer to the following:

1a. Which regulations does your state follow for depuration?

New, revised NSSP Manual	<u>5</u>
Old NSSP Regulations (from NSSP 1971 Workshop)	<u>3</u>
State Regulations	<u>8</u>

1b. Does your state have a schedule for the sampling of depurated shellfish?

Yes 9 If yes, on what schedule?
No 2

Schedule:

- 1) Each batch by government agency
- 2) 1 sample per 10 bushels
- 3) Monthly or by each batch
- 4) Each lot sampled before sale
- 5) After shakedown monthly
- 6) Frequent

7) <u>Process Water</u>	<u>Shellfish Meats</u>
Raw 0-hour	0-hour

Treated 0-hour	
Treated 24-hour	24-hour (3 samples/lot)
Treated 48-hour	48-hour (3 samples/lot)

- 8) Before Depuration - ≥ 1 sample (12 or more shellfish per sample for bacterial exam)
24 hour - ≥ 3 samples randomly selected from ≥ 3 locations in each tank
After Depuration - repeat 24 hour schedule.
- 9) Weekly

It should be noted that two states who responded YES, their state allows depuration, stated that it is not economically feasible at the present time. They do not have any depuration processors yet and did not indicate a sampling schedule.

If No, please refer to the following:

1c. Why is depuration not being practiced in your state?

A list of responses follows:

- 1) Not presently economically feasible (3 states);
- 2) Strong local opposition;
- 3) Limited resource in restricted area; technology appears questionable
- 4) Presently do not have authority to allow depuration;
- 5) Not enough manpower to oversee;
- 6) Good water quality at growing and harvest areas makes it unnecessary;
- 7) Not yet requested; Question has never come up; Generally not needed;
- 8) Have not adopted regulations

1d. Is your state planning to begin depuration within the next 1 to 2 years?

Yes 2

Other responses gave the following results: one state did not know; one stated possibly, as this is currently in the policy development stage; and one indicated that depuration would be used as need dictates when in compliance with the Manual.

No 5

Why not? -- Not enough manpower to oversee;
No one has approached the state

1e. If yes, why has your state decided to allow depuration?

Four responses given:

- 1) Now have interest;
- 2) Have written new rules taken from the FDA/ISSC Model Rules, which include depuration;
- 3) Anticipate an increase in need for use of the depuration process as time goes on;
- 4) Depuration is the only provision practical/allowable in order for the local shellfish producer to sell its product.

Discussion of the Results

Study of the administrative organization of State programs lends itself first to the identification of the agencies that carry out the various State responsibilities, and second to the question of how each agency groups its forces and assigns its tasks in seeking to accomplish its mission. Thus administrative organization has to do with the framework for using available staff and for applying financial and physical resources.

Part of the approach taken in this study was to view the administrative organization of State shellfish programs in respect to the framework they use toward efficient management of State shellfish resources.

The protection of consumers with respect to shellfish sanitation requires an essential unity of approach to management techniques and strategies, both among the various operational practices used and between health and economic concerns. The occurrence of overlapping, duplication, and conflicting requirements is likely to arise when attempts are made at protecting the consumer, especially when separate administrative agencies share related tasks. In managing state shellfish programs this is especially a potential problem, as the organization and operation of such programs is fragmented at state levels in most states. The location of programs ranges through the structure of state

governments in health, natural resources, and other departments.

The effect of the horizontal location in the structure of state government of the agency might effect the general orientation and approach of the agency to its shellfish responsibility. The vertical location of the responsible party for shellfish management in its departmental hierarchy has significance also, primarily in terms of its ability to exercise its powers. As responses indicate, shellfish regulatory officials are two or three steps removed from their department heads in rank. This is undeniably a problem. Administrators in direct-line responsibility above such an official may or may not have a keen interest in his activities or problems. Likewise, at this level the shellfish official may require approval on several levels before he can take certain actions.

Unity of operation can be achieved through improved interstate, intrastate, and intergovernmental relations. Currently interstate relations in the form of interstate agreements, is had by 28% of the states. These agreements are entered into based on the fact that the participating states share an estuary containing shellfish resources. For states not sharing an estuary, participation in interstate agreements does not occur. Neither was participation in any other form of interstate contact indicated by these non-participating states. This implies that an interstate

agreement is based solely on the above criteria of sharing an estuary containing shellfish resources. This limits the number of states involved in this type of interstate contact. Since no other form of contact was indicated, current interstate relations appear to be limited to interstate agreements.

To gain a greater participation among states toward more unified and coordinated state efforts, perhaps the concept of interstate contact should be expanded beyond interstate agreements to incorporate other forms of contact between states. This contact would not be based solely on the geographic resources shared, but on the similarities and differences in approach toward the operational practices used and the implementation of such practices. The full exchange of information among neighboring states, as well as other states, can accomplish this goal. Full exchange means the sharing of successful and unsuccessful strategies, operational practices, patrol and enforcement methods, and research information. Knowledge gained from another state's successes and failures can be applied, where appropriate, to state programs and used by these states to strengthen their individual program.

Intrastate contact was not questioned, but does occur within states through contact with sister agencies and local agencies. Contact with sister agencies is guided by memoranda of understanding. Responsibility for enforcement

activities and laboratory analysis is shared amongst sister agencies in most states.

Contact with local agencies is with local health departments, through the sharing of or dependence upon, local laboratory facilities. In addition, intrastate contact in some states is more formally based with legal authority for enforcement activities given to local police.

The last component toward unity of operation is that of intergovernmental relations between state and federal agencies. Such contact is to provide states with information toward improving the overall operation of their individual programs, as well as components of their state's program. States also gain training and standardization information.

The intergovernmental contact currently participated in with federal agencies is primarily with the Food and Drug Administration. Discussion of current state contact with federal agencies follows question II.1. States also have contact with the Environmental Protection Agency. Frequency of contact with this agency was not asked of the states as this agency has an indirect responsibility to shellfish resources. "The Environmental Protection Agency has the overall responsibility for maintaining and restoring a level of water quality great enough to provide for the protection and propagation of fish, shellfish, and wildlife and allow for recreation in and on the water. In carrying out its

responsibilities, the Environmental Protection Agency works with the states to monitor environmental quality and is responsible for reporting to the Congress on the quality of all the Nation's waters. The Environmental Protection Agency and the Food and Drug Administration share responsibility for establishing safe levels of contaminants in foods." (Memorandum of Understanding on Shellfish Growing Waters, 1985)

A state's principal contact with the Environmental Protection Agency surrounds the occurrence of problems involving agricultural and pesticide runoff into shellfishing waters and maintaining water quality near the point of discharge from wastewater treatment plants located in close proximity to shellfishing waters.

More contact at this level has the potential for greatly improving unity in operation. The current level of contact appears to be low with most agencies, and perhaps leads to less efficiency and effectiveness in the management of state programs. Strengthening of state programs can be facilitated through an increase in coordination between states and the federal government.

Effective use of resources can also achieve unity in operation. The performance of operational procedures was found to be uneven, with many gaps evident; for example, as with the frequency of inspections conducted or the parameters included in water quality monitoring. Although

scarcity of financial resources makes it difficult for most states to increase their performance in these areas, the state commitment should be such that the available resources are utilized to their maximum potential. The need for upgrading personnel, facilities, and approach in many state programs, however, is apparent and much needed.

The unity of operation mentioned above is an essential component to the state role under the Interstate Shellfish Sanitation Conference. Diversity in operational practices has the potential to adversely affect shellfish quality. Significant variations in laboratory procedures or techniques, for example, might lead to wide variations in the results. If reliable results are to be obtained it is essential that standardized procedures be used.

Response indicates that states are in compliance with this procedural guideline as outlined in the Manual of Operations. A point of contention, however, is the doubt of some States as to the validity of the standard given. To these states the criteria are outdated and not scientifically supported. Diversity by states in implementing this guideline will lead to obvious problems in the control of shellfish.

Though the standard must be followed by states, the question of its validity must continually be researched until such evidence is found to either support the current standard or refute it.

Summary of the Results

The results are presented in terms of responses to the questionnaire and interpretation of the implications of these responses. No attempt is made at cross-referencing the separate responses or more complex analyses. The information at this first level of analysis is useful and informative.

The summary of the basic results of this study dealing with the organization and management of state shellfish programs, is presented below under the appropriate objective answered.

Objective 1: To determine whether states are functioning within the general framework of the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference.

- 1) States are functioning within the general framework outlined for them by the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference. Variability exists, however, in the implementation of the duties outlined. This variability stems from the individual state's interpretation of the guidelines set forth for shellfish management and is based on conditions particular to the state in question. Such variability is seen primarily among the duties requiring updates of information, such as inspection of packing/processing

plants, surveying of waters, and sampling of shellfish meat and growing water sample information.

- 2) In carrying out their designated duties, states have varying degrees of contact with federal agencies. Contact is most usually had with the Food and Drug Administration. Other agencies in contact with states, though with less frequency, are the National Oceanic and Atmospheric Administration and its National Marine Fisheries Service, and the Environmental Protection Agency.
- 3) States do allow depuration, but interest and economic feasibility on the part of industry has been low. Those states currently carrying out depuration follow the 1986 revision of the Manual of Operations and State regulations. Seventeen percent use the old National Shellfish Sanitation Program regulations (from the 1971 workshop). Currently the primary method of shellfish purification used by states is relaying. Forty-seven percent of the states share this responsibility with industry.

Objective 2: To determine what differing techniques and strategies state shellfish programs utilize in carrying out their National Shellfish Sanitation Program and Interstate Shellfish Sanitation Conference duties.

- 1) States utilize primarily from one to two main strategies toward better managing their shellfish resources. Those strategies most used include:
(a) environmental quality standards, criminal court action, and shellfish task forces; and (b) interstate agreements, guided primarily by nonformalized agreement.
- 2) States using the strategies consider those they have chosen to be effective for maintaining the quality of state shellfish as well as shellfish growing waters.

Objective 3: To determine whether a stronger or different state role is needed to regulate shellfish.

- 1) A stronger state role is felt to be needed by 39% of the respondents. This can be facilitated through several avenues: an increase in funding and staff; strengthening of fines for illegal harvest; greater state response to the shellfish industry; greater state response to harvesting area closures.
- 2) A stronger state role is not felt to be needed by 44% of the respondents. The accomplishment of the current directives and requirements by states is felt to be sufficient. States are satisfied with their role in the Interstate Shellfish Sanitation Conference.
- 3) A different state role is not felt to be needed at this time, as states are satisfied with their role in the

Conference as stated above. A different role in terms of increased requirements for states would not be feasible at this time as states currently need more manpower and funding to accomplish the present requirements.

Objective 4: To identify major obstacles to state action towards shellfish.

- 1) Major obstacles toward shellfish management at the state level can be categorized into 4 main areas:
 - 1) Administrative/Operating Constraints
 - 2) Legal Constraints
 - 3) Technical/Analytical Constraints
 - 4) Public Constraints

The most frequent obstacle encountered is that of insufficient resources (funding, staff, and labs). The most serious obstacle is that of doubt surrounding the validity of the bacteriological indicator used and the claim that the current 1986 revision of the Manual of Operations has major deficiencies (criteria outdated and generally not scientifically supported).

Other frequent obstacles encountered include the low priority of shellfish as related to other issues in state government, coastal development and competing users, and low fines for prohibited violations.

CHAPTER VI

CONCLUSIONS

The analysis and interpretations of the results of the research appear to warrant the conclusions characterized below.

1) States need an increase in resources (especially funding and staff) to better fulfill their duties as delineated in the National Shellfish Sanitation Program Manual of Operations.

2) An increase in public and legislative awareness toward shellfish concerns is needed.

3) State doubt in the validity of the current bacteriological standard poses a severe problem in respect to the management of shellfish resources.

4) There is a strong need for a realistic and continuing evaluation of the state role in shellfish management. Such an evaluation should encompass a thorough examination of the needs in respect to basic uniformity of policy, operational practices, and approach, and for full cooperation among states, the Food and Drug Administration, and the shellfish industry.

5) Full exchange of information among neighboring states on their problems, findings, and practices would be effective in terms of aiding the coordination of state efforts.

CHAPTER VII
FINDINGS AND RECOMMENDATIONS

Findings

The results and conclusions of the study would appear to warrant the implications set forth below.

- 1) There is a need for greater interstate and intergovernmental contact.
- 2) The history of the Conference indicates that it is possible to coordinate state, industry, and federal efforts into a viable organization with effective outcomes.
- 3) Variations in the use of operational practices seemed to be dependent on individual state characteristics in some cases.
- 4) Scientific research to support any standards (bacteriological or otherwise) used by states should be updated periodically to insure the safety of shellfish.

Recommendations

- 1) State shellfish programs should be strengthened through an effective legal base, sensible organization and management, and financial, human, and facility resources sufficient to the tasks required.
- 2) States should utilize local resources where available to aid in implementing the five functional duties.
- 3) States should increase intergovernmental coordination where possible.
- 4) States should promote the education of the general public and industry of shellfish hazards, problems, and concerns.
- 5) States should provide to the best of their ability, information to acquaint industry with its laws and regulations, including those in force and those under consideration. Dissemination of such information should be formalized so industry knows where and when to expect this information.

CHAPTER VIII

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APPENDICES

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- Appendix 1: Public Health Service, National Shellfish Sanitation Program Manual of Operations, Part I (1987), and Part II (1986)
- Appendix 2: Public Health Service, National Shellfish Sanitation Program Manual of Operations, Part I (1987)
- Appendix 3: U.S. General Accounting Office, "Monitoring and Enforcing Food Safety -- An Overview of Past Studies," September 9, 1983.
- Appendix 4: U.S. General Accounting Office, "Monitoring and Enforcing Food Safety -- An Overview of Past Studies, " September 9, 1983.
- Appendix 5: Public Health Service, National Shellfish Sanitation Program Manual of Operations, Part I (1987).

APPENDIX 1
DEFINITION OF TERMS

Adequate -- that which is needed to accomplish the intended regulatory purpose in keeping with good public health practice.

Approved -- the classification of a State shellfish growing area which has been approved by the State shellfish control authority for growing or harvesting shellfish for direct marketing. The classification of an approved area is determined through a sanitary survey conducted by the State shellfish control authority in accordance with Part I, Section C of the National Shellfish Sanitation Program Manual of Operations, Part II. An approved classified growing area may be temporarily made a closed area when a public health emergency is declared, such as a hurricane or flooding.

Certification Number -- the number assigned by the State shellfish control agency to each certified shellfish dealer. It consists of a one to five digit number preceded by the two letter state abbreviation and followed by the two letter symbol designating the type of operation certified.

Closed Area -- a growing area where the harvesting of shellfish is temporarily or permanently not permitted. A

closed area status is or may be placed on any of the four classified area designations: approved, conditionally approved, restricted, or prohibited.

Coliform Group -- The coliform group includes all of the aerobic and facultative anaerobic, Gram-negative, non-spore-forming bacilli which ferment lactose with gas formation within 48 hours at 35 degrees Celsius.

Conditionally Approved Area -- the classification of a State shellfish growing area determined by the State shellfish control authority to meet approved criteria for a predictable period. The period is conditional upon established performance standards specified in a management plan. A conditionally approved shellfish growing area is closed by the shellfish control authority when it does not meet the approved growing area criteria.

Container Relaying -- the transfer of shellfish from restricted areas to approved or conditionally approved areas for natural biological cleansing in a container using the ambient environment as a treatment system.

Controlled Purification or Depuration -- the process of using a controlled, aquatic environment to reduce the level of bacteria and viruses in live shellfish.

Dealer -- a commercial shellfish shipper, reshipper, shucker-packer, repacker, or depuration processor or operation.

Depletion -- the removal of all existing commercial quantities or market-size shellfish from a prohibited area.

Depuration Plant -- a facility of one or more depuration units. A depuration unit is a tank or series of tanks supplied by a single process water system.

Depuration Processor -- a person who receives shellstock from approved or restricted growing areas and submits such shellstock to an approved controlled purification process.

Dry Storage -- the storage of shellfish out of water.

Fecal Coliform Group -- bacteria of the coliform group which will produce gas from lactose in a suitable multiple tube procedure liquid medium (EC or A-1) within 24 hours (± 2 hours) at 44.5 degrees Celsius (± 0.2 degrees) in a water bath.

Growing Area -- an area which supports or could support live shellfish.

Harvester -- a person who takes shellfish by any means from a growing area.

Intergovernmental Practices -- management practices to coordinate control efforts of two or more governmental agencies in the maintenance of healthy shellfish resources and growing areas. Intergovernmental practices can be used between neighboring states sharing shellfish growing areas or through interaction between federal and State agencies.

Interstate Shellfish Sanitation Conference -- the tripartite organization between the federal government, States, and the shellfish industry that develops recommended policies and guidelines for the sanitary control of the shellfish industry.

Interstate Shellfish Sanitation Conference Region -- geographical grouping of shellfish producing States with similar characteristics and interests, established to provide for fairly distributed representation. The Interstate Shellfish Sanitation Conference Regions shall be:

Region 1--Maine, New Hampshire, Massachusetts, Rhode Island
Region 2--Connecticut, New York, New Jersey
Region 3--Maryland, Pennsylvania, Delaware, Virginia
Region 4--North Carolina South Carolina, Georgia, Florida
Region 5--Alabama, Mississippi, Louisiana, Texas
Region 6--Alaska, Washington, Oregon, California, Hawaii

Label -- any written, printed, or graphic matter affixed to or appearing upon any package containing shellfish.

License -- the document issued by the appropriate State shellfish control agency which authorizes a person to harvest and transport shellfish for commercial sale.

Lot of Shellstock -- a collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area by one or more harvesters.

Lot of Shellstock for Depuration -- shellstock harvested from a particular area at a particular time and delivered to one depuration plant.

Marine Biotoxins -- poisonous compounds accumulated by shellfish feeding upon toxic microorganisms. The poisons may come from dinoflagellates; e.g., Gonyaulax cantenella, G. tamarensis, and Etychodicus brevis (formerly Gymnodinium breve).

Memorandum of Understanding -- a written document between two or more agencies defining each agency's responsibilities in administering the shellfish control program. Memoranda of Understanding are entered into by federal agencies which share responsibility for shellfish resources as well as by State agencies.

National Shellfish Sanitation Program -- the cooperative state-federal-industry program for certification of interstate shellfish shippers as described in the National Shellfish Sanitation Program Manual of Operations, Parts I and II. Foreign governments may be members by having a current Memorandum of Understanding or agreement with the Food and Drug Administration.

Operational Practices -- management practices used by State control and State patrol agencies to carry out their duties of operation in accordance with the provisions of the National Shellfish Sanitation Program Manual of Operations, Parts I and II. Such duties include classifying growing

areas, conducting sanitary surveys, inspecting packing and processing plants, laboratory analyses, and enforcement activities.

Person -- an individual, partnership, corporation, association, or other legal entity.

Poisonous or Deleterious Substance -- a toxic compound occurring naturally or added to the environment that may be found in shellfish and for which a regulatory tolerance limit has been or may be established to protect public health. Examples of naturally occurring substances would be paralytic shellfish toxins and trace elements geologically leached from the environment, such as mercury. Examples of added substances would be agricultural pesticides and polynuclear aromatics from oil spills.

Process Batch -- a quantity of shellfish used to fill each separate depuration unit.

Process Water -- the water in depuration tanks during the time that shellfish are being depurated.

Prohibited Area -- State waters that have been classified by the State control agency as prohibited for the harvesting of shellfish for any purpose except depletion. A prohibited classification area is closed for harvesting shellfish at all times.

Processor -- a person who depurates, shucks, packs, or repacks shellfish.

Relaying -- The transfer of shellfish from restricted areas to approved areas for natural biological cleansing using the ambient environment as a treatment system.

Repacker -- a person other than the original certified shucker-packer who repacks shucked shellfish into other containers.

Reshipper -- a person who purchases shucked shellfish or shellstock from other certified shippers and sells the product without repacking or relabeling to other certified shippers, wholesalers or retailers.

Restricted Area -- State waters that have been classified by the State shellfish control agency as an area from which shellfish may be harvested only if permitted and subjected to a suitable and effective purification process.

Sanitary Survey -- the evaluation of all actual and potential pollution sources and environmental factors having a bearing on shellfish growing area water quality.

Shellfish -- all edible species of oysters, clams, or mussels; either shucked or in the shell; fresh or frozen; whole or in part. Some of the bivalves included in this definition are listed in Appendix 2.

Shellfish-producing State -- a state having shellfish growing waters in its jurisdiction and having certified shellfish plants for the initial processing of shellfish.

Shellstock -- shellfish in the shell.

Shucked Shellfish - shellfish, whole or in part, from which one or both shells have been removed.

State Shellfish Control Agency -- the State agency or agencies having legal authority to classify shellfish growing areas and issue permits for the interstate shipment of shellfish in accordance with the provisions of the National Shellfish Sanitation Program Manual of Operations, Parts I and II.

State Shellfish Patrol Agency -- the State agency having responsibility for the enforcement of laws concerning harvesting of shellfish.

State Waters -- waters that belong wholly to an individual State including the Territorial Sea (0 to 3 mile limit or other limits as may be claimed by some States).

Worst Pollution Conditions -- conditions determined by changes in meteorological, hydrographic, seasonal, and point source conditions that have been historically demonstrated to adversely impact a particular growing area.

APPENDIX 2:

LIST OF COMMON BIVALVES INCLUDED AS SHELLFISH

COMMON NAME	SCIENTIFIC NAME
Cockle,	<u>Clinocardium nuttalli</u> <u>Cardium corbis</u> (Pacific)
Geoduck	<u>Panope generosa</u>
Freshwater clam	<u>Rangia cuneata</u>
Soft shell clam	<u>Mya arenaria</u>
Hard or quahog clam	<u>Mercenaria mercenaria</u> <u>Mercenaria campechiensis</u>
Surf clam	<u>Spisula solidissima</u>
Mahogany or Ocean quahog, clam	<u>Arctica islandica</u>
Gaper or Horse clam	<u>Tresus nuttalli</u> and <u>T. capax</u>
Razor clam	<u>Solen resaceus</u> , <u>Ensis directus</u> (Atlantic) <u>Solen viridis</u> , <u>Tagelus plebeius</u> and <u>Siliqua patula</u> (Pacific)
Bent-nose clam	<u>Macoma nasuta</u> .
Pismo clam	<u>Tivela stultorum</u> .
Butter clam	<u>Saxidomus giganteus</u> .
Calico clam,	<u>Macrocallista maculata</u> .
Sunray venus,	<u>Macrocallista nimbosa</u> .
Pacific littleneck clam	<u>Protothaca tenerrima</u> and <u>Protothaca staminea</u> .
Manila clam,	<u>Tapes semidecussata</u> .
Pacific (Japanese) oyster	<u>Crassostrea gigas</u>
Eastern oyster	<u>Crassostrea virginica</u> .
Olympia or yaquina oyster	<u>Ostrea lurida</u> .
European oyster	<u>Ostrea edulis</u> .
Blue or bay mussel	<u>Mytilus edulis</u> .
California sea mussel,	<u>Mytilus californianus</u>
Green lipped mussel,	<u>Perna canaliculus</u> (New Zealand).

APPENDIX 3

MAJOR FOOD SAFETY-RELATED PROGRAMS

I. U.S. DEPARTMENT OF AGRICULTURE

<u>Acts and Sections</u>	<u>Program Description</u>	<u>Administering Organization</u>
PROGRAM: <u>Egg and Egg Products Inspection</u>		
Egg Products Inspection Act	To assure that eggs and egg products are wholesome, unadulterated, and properly labeled.	Agricultural Marketing Service
PROGRAM: <u>Meat and Poultry Inspection</u>		
Federal Meat Inspection Act; Wholesome Meat Act; Poultry Products Inspection Act	To prevent the sale and distribution of adulterated or misbranded meat and poultry products.	Food Safety and Inspection Service

II. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**PROGRAM: Food Sanitation and Quality Control**

Food, Drug, and Cosmetic Act, 402, 702, 702(a), 704	To prevent food from being sold at consumer markets that is hazardous to human health because of microbiological contamination, filth, decomposition, or foreign objects. This objective is pursued through inspections and other enforcement activities, development of manufacturing guidelines, industry consultation, and research to identify new hazards and improve their detection and control.	Food and Drug Administration
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<u>Acts and Sections</u>	<u>Program Description</u>	<u>Administering Organization</u>
PROGRAM: <u>Food and Color Additives</u>		
Food, Drug, and Cosmetic Act, 402, 409, 706	To ensure the safety of ingredients added to foods, whether they are added directly or indirectly. FDA reviews food additive petitions and Generally Recognized as Safe affirmation petitions, and conducts research to evaluate the safety of additives already marketed.	Food and Drug Administration
PROGRAM: <u>Chemical Contaminants</u>		
Food, Drug, and Cosmetic Act, 402, 406, 408	To identify and prevent health hazards of chemical contaminants in food such as industrial chemicals, pesticides, heavy metals, and natural toxicants such as aflatoxin. FDA conducts research, surveys food to detect and prevent contaminants, and establishes regulatory levels (except pesticide tolerances which are established by EPA).	Food and Drug Administration
PROGRAM: <u>Nutrition</u>		
Food, Drug, and Cosmetic Act, 403, 411, 412	To assure the nutritional quality of foods through development of guidelines on nutrient composition, regulations on nutrition labeling and dietary claims, and research on nutrient requirements, safety, and bioavailability. Specific statutory requirements apply to the composition and	Food and Drug Administration

monitoring of infant
formulas.

<u>Acts and Sections</u>	<u>Program Description</u>	<u>Administering Organization</u>
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PROGRAM: Interstate Travel

Food, Drug, and Cosmetic Act, 402	To assure the safety of food and water used or transported on inter- state conveyances, and to prevent the spread of communicable disease, by conducting inspections of interstate aircraft, buses, trains, vessels, and trucks.	Food and Drug Administra- tion
Public Health Service Act, 311, 361, 368		

PROGRAM: Food Service, Shellfish, and Milk Safety

Food, Drug, and Cosmetic Act, 401, 402	To provide for FDA coordination of state activities in the areas of food service inspec- tion, shellfish safety, and milk safety, through research, technical assistance, promotion of uniform sanitation standards, and coopera- tive programs such as the National Shellfish Sani- tation Program and the Interstate Milk Shippers Certification Program.	Food and Drug Administra- tion
Public Health Service Act, 301, 311, 361		

PROGRAM: Food Economics

Food, Drug, and Cosmetic Act, 401, 402, 403	To prevent economic de- ception of the consumer brought on by partially filled containers, foods that do not meet standards, and inadequate food labeling. FDA develops and revises food standards for specific foods, develops and enforces labeling regulations, and conducts limited surveill- ance to prevent economic	Food and Drug Administra- tion
Tea Importation Act		
Fair Packaging and Labeling Act, 4, 5		

adulteration and misbranding.
 FDA also sets standards for
 and samples all imported tea.

<u>Acts and Sections</u>	<u>Program Description</u>	<u>Administering Organization</u>
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PROGRAM: Safety of Animal Derived Human Foods

Food, Drug, and Cosmetic Act, 512	To ensure that drug and chemical residues which are a risk to human health are not found in edible animal tissue, FDA participates in various programs to detect drug residues, pesticides, and industrial chemicals in meat for human consumption; and conducts research on the toxicity of veterinary drugs in food animals.	Food and Drug Administration
--------------------------------------	--	------------------------------

PROGRAM: Animal Feed Safety

Food, Drug, and Cosmetic Act, 402 403, 409, 501, 502, 512, 702, 704	To ensure that animal foods are not adulterated or misbranded and are safe and effective, and that harmful residues do not enter the human food supply. This is accomplished through medicated feed mill inspections and other enforcement activities and through research on the transfer of drug resistance from animal to man.	Food and Drug Administration
--	---	------------------------------

PROGRAM: New Animal Drug Evaluation

Food, Drug, and Cosmetic Act, 409, 501, 510, 512	To ensure that animal drugs and feed additives are safe and effective, FDA reviews New Animal Drug Applications (NADAs), Investigational NADAs, Feed Additive Petitions,	Food and Drug Administration
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<u>Acts and Sections</u>	<u>Program Description</u>	<u>Administering Organization</u>
	and conducts research to evaluate the effects of drugs in animals.	

PROGRAM: Animal Drugs: Bioresearch Monitoring

Food, Drug, and Cosmetic Act, 406, 408, 409, 512, 701(a), 702, 704, 706	To ensure that clinical and nonclinical investigations are conducted in a scientific manner that will demonstrate safety and effectiveness of animal drugs to the target species and safety to the consumer, FDA inspects clinical investigators and animal drug sponsors and evaluates all bioresearch data submitted to determine validity and accuracy.	Food and Drug Administration
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III. ENVIRONMENTAL PROTECTION AGENCY

PROGRAM: Registration Standards

Federal Insecticide, Fungicide, and Rodenticide Act, 3	To develop registration standards for active and inert ingredient chemicals to facilitate registration of currently registered pesticides and registration of new pesticides.	Office of Pesticide Programs
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PROGRAM: Rebuttable Presumption Against Registration

Federal Insecticide, Fungicide, and Rodenticide Act, 3	To evaluate pesticides which have an identified potential for producing significant adverse health or environmental effects	Office of Pesticide Programs
--	---	------------------------------

PROGRAM: Special Registration

Federal Insecticide, Fungicide, and Rodenticide	Activities include State and Federal experimental use per-	Office of Pesticide Programs
---	--	------------------------------

Act, 5, 18, 24(c) Food, Drug, and Cosmetic Act, 408	mits; preparation and review of regulations for State registrations; emer- gency exemptions; special local needs registration and temporary tolerances.
---	--

<u>Acts and Sections</u>	<u>Program Description</u>	<u>Administering Organization</u>
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PROGRAM: Tolerances

Food, Drug, and Cosmetic Act, 402, 408, 409	To establish tolerances (maximal pesticide residue limits permis- sible) or exemptions from tolerance require- ments for pesticides used on food and feed crops.	Office of Pesticide Programs
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PROGRAM: Pesticide Use Management

Federal Insecti- cide, Fungicide, and Rodenticide Act; No specific sections except sections 22 and 23 concerning cooperation with States	Program includes con- sultation and the ex- change of information and technical advice between the Agency and Federal, State, and local officials with interests in pesticide regulations, as well as assistance to pesticide users, pesticide pro- ducers, and the general public to promote com- pliance with pesticide regulations and safe use practices.	Office of Pesticide Programs
--	--	------------------------------------

PROGRAM: Registration

Federal Insecti- cide, Fungicide, and Rodenticide Act, 3	To register new pesti- cide products and amendments to add uses and/or new formulations for currently registered pesticides.	Office of Pesticide Programs
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APPENDIX 4

A CHRONOLOGY OF
FOOD SAFETY AND RELATED LEGISLATION

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1897	Tea Importation Act, 29 Stat. 604 (Mar. 2, 1897)	Requiring imported tea to be examined for purity, quality, and fitness for consumption.
1906	Food and Drugs Act of 1906, 34 Stat. 768 (June 30, 1906)	An act to regulate manufacture, sale, or transportation of adulterated or misbranded food, drugs, and drinks in interstate commerce.
1906	Meat Inspection Act of 1906, 34 Stat. 669 (June 30, 1906)	Mandating post-mortem inspection of carcasses for transportation or sale in interstate commerce of cattle, sheep, swine, and goats for human consumption.
1907	Meat Inspection Act of 1907, 34 Stat. 1256 (Mar. 4, 1907)	Same statute as above.
1910	Insecticide Act of 1910, 36 Stat. 331 (Apr. 26, 1910)	An act to regulate the manufacture, sale, or transportation of misbranded or adulterated insecticides or fungicides.
1912	Act of August 23, 1912, 37 Stat. 416 (Sherley Amendment)	Amendments to Food and Drugs Act of 1906 to cover mislabeling of the curative and therapeutic effects of food or drugs.
1913	Act of March 3, 1913, 37 Stat. 732 (Net Weight Amendment)	Amendments to Food and Drugs Act of 1906 to require labeling as to quantity.

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1927	Import Milk Act, 44 Stat. 1101 (Feb. 15, 1927)	Requiring imported milk and cream to be sanitary and meet certain specified conditions.
1930	McNary-Mapes Amendment (Pure Foods), 46 Stat. 1019 (July 8, 1930)	Amending Food and Drugs Act of 1906 to cover standards of quality and fill for canned goods.
1938	Wheeler-Lea Act, 52 Stat. 111, 114 (Mar. 21, 1938)	Amending Federal Trade Commission Act to control false advertising of food, drugs, cosmetics, and therapeutic devices.
1938	Federal Food, Drug, and Cosmetic Act of 1938, Public Law 75-717, 52 Stat. 1040	An act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for related purposes.
1938	Act of June 29, 1938, Public Law 75-776, 52 Stat. 1235	Amending Meat Inspection Act of 1907 to clarify definitions, marking requirements, and penalties.
1942	Act of June 10, 1942, Public Law 77-602, 56 Stat. 351	Amending Meat Inspection Act of 1907 to facilitate Federal meat inspection of meat-packing establishments engaged in intrastate commerce during duration of World War II.
1944	Department of Agriculture Organic Act of 1944, Public Law 78-425, 58 Stat. 734 (Sept. 21, 1944)	Among other things, provides for control and eradication of certain animal and plant pests.

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1946	Agricultural Marketing Act of 1946, Public Law 79-733, title II, 60 Stat. 1087 (Aug. 14, 1946)	Among other things, authorizes Secretary of Agriculture to develop and improve standards of quality, condition, and grade, and to inspect and certify agricultural products as to class, quality, and condition.
1947	Federal Insecticide, Fungicide, and Rodenticide Act of 1947, Public Law 80-104, 61 Stat. 163 (June 25, 1947)	To regulate the marketing of certain economic poisons, including proper labeling and registering thereof.
1953	Federal Food, Drug and Cosmetic Act Amendments of 1953, Public Law 83-217, 67 Stat. 476 (Aug. 7, 1953)	To authorize factory inspections without manufacturers' consent under certain conditions.
1954	Pesticide Chemicals Act, Public Law 83-518, 68 Stat. 511 (July 22, 1954)	Amending Federal Food, Drug, and Cosmetic Act to regulate levels of residues of pesticide chemicals in or on raw agricultural products.
1956	Fish and Wildlife Act of 1956, Public Law 84-1024, 70 Stat. 1119 (Aug. 8, 1956)	Transferring to the Secretary of the Interior certain functions of the Secretaries of Agriculture and Commerce, among them all functions pertaining to fish, shellfish and any other such products; included development and promulgation of grade standards, inspection and certification, and improvement in transportation facilities and rates.

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1957	Poultry Products Inspection Act of 1957, Public Law 85-172, 71 Stat. 441 (Aug. 28, 1957)	To prevent the movement in interstate or foreign commerce of unwholesome or adulterated poultry or poultry products through mandatory ante- and post-mortem inspection of poultry.
1958	Food Additives Amendment of 1958, Public Law 85-929, 72 Stat. 1784 (Sept. 6, 1958) (Delaney Amendment)	Amending Federal Food, Drug, and Cosmetic Act to regulate and define food additives and to prohibit use of additives unsafe to the health of man or animal.
1959	Nematocide, Plant Regulator, Defoliant and Dessicant Amendment of 1959, Public Law 86-139, 73 Stat. 286 (Aug. 7, 1959)	To expand scope of Federal Insecticide, Fungicide, and Rodenticide Act and scope of 1954 amendments to Federal Food, Drug, and Cosmetic Act to include newly developed chemical pesticides.
1960	Color Additive Amendments of 1960, Public Law 86-618, 74 Stat. 397 (July 12, 1960)	Amending Federal Food, Drug, and Cosmetic Act to regulate and define color additives and to prohibit use of additives unsafe to the health of man or animal.
1962	Drug Amendments of 1962, Public Law 87-781, 76 Stat. 780 (Oct. 10, 1962)	Amending Federal Food, Drug, and Cosmetic Act to require FDA to affirmatively approve marketing of new drug.

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1962	Talmadge-Aiken Act of 1962, Public Law 87-718, 76 Stat. 663 (September 28, 1962)	Authorizing USDA to establish cooperative arrangements with States in administering and enforcing Federal laws relating to marketing agricultural products and eradicating plant and animal diseases.
1964	Act of May 12, 1964, Public Law 88-305, 78 Stat. 190	Amending Federal Insecticide, Fungicide, and Rodenticide Act to, among other things, eliminate practice of protest registration permitting manufacturers to market economic poisons notwithstanding USDA's refusal to register.
1966	Fair Packaging and Labeling Act, Public Law 89-755, 80 Stat. 1296 (Nov. 3, 1966)	Preventing the use of unfair or deceptive methods of packaging or labeling certain consumer commodities, including food and drugs distributed in interstate or foreign commerce.
1967	Wholesome Meat Act of 1967, Public Law 90-201, 81 Stat. 584 (Dec. 15, 1967)	Revised Federal Meat Inspection Act to authorize cooperation with State meat inspection programs, including financial assistance up to 50 percent of State program costs; to authorize regulation of meat storage and handling to prevent adulteration and misbranding; and for other purposes.

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1968	Animal Drug Amendments of 1968, Public Law 90-399, 82 Stat. 342 (July 13, 1968)	Amending Federal Food, Drug, and Cosmetic Act to consolidate and clarify requirements applicable to animal drugs.
1968	Wholesome Poultry Products Act of 1968, Public Law 90-492, 82 Stat. 791 (Aug. 18, 1968)	Revised Poultry Products Inspection Act to authorize cooperation with State poultry inspection programs and for other purposes.
1970	Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15623, 84 Stat. 2086 (Dec. 2, 1970)	Among other things, transferring to EPA FDA's pesticide tolerance-setting authority, USDA's pesticide registration authority, and Interior's pesticide research authority.
1970	Egg Products Inspection Act of 1970, Public Law 91-597 84 Stat. 1620 (Dec. 29, 1970)	Providing for restrictions on disposition of certain egg products, uniformity of standards for eggs in interstate and foreign commerce, inspection of certain egg products, and for other purposes.
1972	Federal Environmental Pesticide Control Act of 1972, Public Law 92-516, 86 Stat. 973 (Oct. 21, 1972)	Revising Federal Insecticide, Fungicide and Rodenticide Act to, among other things, require registration of pesticides, including ones sold intrastate, and to provide for national monitoring program for pesticide residues.

<u>Year</u>	<u>Statute</u>	<u>Provisions</u>
1976	Act of March 15, 1976, Public Law 94-231, 90 Stat. 215	Amending Department of Agriculture Organic Act of 1944 to clarify authority of Secretary of Agriculture to control and eradicate plant pests, and for other purposes.
1976	Toxic Substances Control Act of 1976, Public Law 94-582, 90 Stat. 2867 (Oct. 21, 1976)	Authorizing regulation of commercial chemicals not adequately addressed by other regulatory controls and programs.
1976	United States Grain Standards Act of 1976, Public Law 94-582, 90 Stat. 2867 (Oct. 21, 1976)	Amending U.S. Grain Standards Act of 1916 to establish the Federal Grain Inspection Service in USDA to administer inspection and weighing requirements, to prescribe and collect inspection fees, and for other purposes.
1977	Food and Agriculture Act of 1977, Public Law 95-113, Sec. 1602, 91 Stat. 1025 (Sept. 29, 1977)	Amending fee-setting authority to exclude administrative and supervisory costs of grain weighing and inspection service.
1978	Federal Pesticide Act of 1978, Public Law 95-396, 92 Stat. 819 (Sept. 30, 1978)	Amending Federal Insecticide, Fungicide, and Rodenticide Act to, among other things, expedite registration and classification of pesticides.
1980	Infant Formula Act of 1980, Public Law 96-359, 94 Stat. 1190 (Sept. 26, 1980)	Amending the Food, Drug, and Cosmetic Act to give FDA regulatory authority over the processing, manufacturing, quality control procedures, and testing of infant formulas.

APPENDIX 5

**LIST OF PREVIOUS EDITIONS OF MANUAL OF OPERATIONS FOR
NATIONAL SHELLFISH SANITATION PROGRAM - NOW SUPERSEDED**

- 1925. Supplement No. 53 to Public Health Reports November 6, 1925
"Report of Committee on Sanitary Control of Shellfish Industry
in the United States".
- 1937. U.S. Public Health Service Minimum Requirement for Approval
of State Shellfish Control Measures and Certification for
Shippers in Interstate Commerce (Revise October 1937).
- 1946. Manual of Recommended Practice for Sanitary Control of the
Shellfish Industry Recommended by the U.S Public Health
Service (Public Health Bulletin No. 295).
- 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 (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).
- 1965. National Shellfish Sanitation Program Manual of Operations Part
I Sanitation of Shellfish Growing Areas, Public Health Service
Publication No. 33, revised 1965.
- 1965. National Shellfish Sanitation Program Manual of Operations Part
II Sanitation of the Harvesting and Processing of Shellfish,
Public Health Service Publication No. 33, revised 1965.
- 1965. National Shellfish Sanitation Program Manual of Operations Part
III Public Health service Appraisal of State Shellfish Sanitation
Programs, Public Health Service Publication No. 33, revised
1965.

APPENDIX 6

COVER LETTER, FOLLOW-UP NOTE,
INITIAL MAILING LIST OF 23 STATES
TITLE PAGE TO QUESTIONNAIRE
QUESTIONNAIRE



THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

The School of Public Health
Department of
Environmental Sciences and Engineering

The University of North Carolina at Chapel Hill
Rosenau Hall 201 H
Chapel Hill, N.C. 27514

Phone: (919) 966-3849

April 24, 1987

Dear

The consumption of raw shellfish from contaminated waters has been a public health concern for many years. This concern has increased in recent years because of reports of shellfish related epidemics in several states. The future of the shellfish industry is directly related to the maintenance of a high level of safety and quality. This study is directed to the management of the safety aspects of State shellfish sanitation programs. The study is being conducted by Ms. Glenda Lewis under my supervision.

Shellfish resources are managed currently under the provisions of the National Shellfish Sanitation Program (NSSP) and The Interstate Shellfish Sanitation Conference (ISSC). States participating in these programs agree to perform specified duties and assume certain responsibilities to insure the production of shellfish of satisfactory quality and safety.

Insights into the operation and management of the State shellfish sanitation programs is important for an understanding of the present status of shellfish control, and a necessity for future program planning. The attached questionnaire is designed to gather information about your agency's programs, responsibilities, management methods and policies in respect to shellfish sanitation. Information and reports deriving from the study will not refer by name or title to individual states or to specific programs. A stamped and addressed envelope is enclosed for your convenience in returning the completed questionnaire.

We appreciate your help in this project. The questionnaire is reasonably short and the questions, hopefully, are clear and readily answerable. We would be pleased to send you a copy of the report of this study. The questionnaire has a place for you to designate whether you want the report of the findings of the study.

Again, your participation in this study is appreciated. We know that any questionnaire requires time and effort.

Please telephone or write if you have any questions about the study. Ms. Lewis can be reached at (919) 933-3490 and I can be reached at (919) 966-3849.

Sincerely yours,

Morris A. Shiffman
Professor and Deputy Chairman



THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

The School of Public Health
Department of
Environmental Sciences and Engineering

The University of North Carolina at Chapel Hill
Rosenau Hall 201 H
Chapel Hill, N.C. 27514
Phone: (919) 966-3849

May 29, 1987

Dear :

A few weeks ago Dr. Morris Shiffman and I sent you a questionnaire on the operation and management of your state's shellfish sanitation program. I have not yet received your completed survey and understand that your daily schedule is busy. However, we need to hear from as many states as possible to achieve meaningful results.

This note is to ask you to complete the survey or forward it to the person(s) responsible for these matters in your state. Upon completion of the study I will be happy to send you a condensation of the results from the corresponding states. Thank you for your cooperation. I look forward to hearing from you soon.

Sincerely,

Glenda Lewis
Graduate Student

gl/m

List to Whom Questionnaires/Letters Were Sent

Mr. John Hurst
Bureau of Marine Sciences
Maine Dept. of Marine Resources
Resources Services Bldg.
West Boothbay Harbor, ME 04575

Mr. Paul Raiche
Bureau of Envr. Health
Dept. of Health & Welfare
6 Hazen Dr.
Concord, NH 03301

Mr. Michael Hickey
18 Route 6A
Sandwich, MA 02563

Mr. Joseph Migliore
Division of Water Resources
209 Cannon Building
75 Davis St.
Providence, RI 02908

Mr. John Volk, Chief
Aquaculture Division
Dept. of Agriculture
State Dock, Rogers Ave.
Milford, CT 06460

Mr. Pieter Van Volkenburgh
Bureau of Shellfish
Dept. of Envr. Conservation
Building #40, SUNNY
Stoney Brook, NY 11794

Mr. William J. Eisele, Jr.
Division of Water Resources
Leeds Point Laboratory
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Mr. Paul DiStefano
Dept. of Health & Mental Hyg.
201 W. Preston St.
P. O. Box 13387
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Mr. Richard Howell
Bureau of Envr. Health
Dept. of Health & Soc. Serv.
Jessee Cooper Bldg.
Dover, DE 19901

Mr. Cloyde W. Wiley
Bureau of Shellfish San.
Va. Dept. of Health
109 Governor St., Room 904
Richmond, VA 23219

Mr. Robert G. Benton
Shellfish Sanitation Program
Dept. of Human Resources
P. O. Box 769
Morehead City, NC 28557

Mr. Ken Moore
SC Dept. of Health & Env. Ctrl
Shellfish Section
2600 Bull St.
Columbia, SC 29201

Dr. Stuart Stevens
Coastal Resources Div.
GA Dept. of Nat. Resources
1200 Glynn Ave.
Brunswick, GA 31520

Mr. John Schneider
Bureau of Marine Research
Dept. of Natural Resources
3900 Commonwealth Blvd.
Tallahassee, FL 32303

Mr. Robert Perkins
Envr. Health Administration
757 Museum Drive
Mobile, AL 36608

Mr. Mark Glatzer
Mississippi Health Dept.
Box 328
Gulfport, MS 39502

Mr. Ron Dugas
LA Wildlife & Fisheries Comm.
400 Royal Street
New Orleans, LA 70160

Mr. Richard E. Thompson
Div. of Shellfish San. Control
Texas Dept. of Health, T-811
1100 W. 49th St.
Austin, TX 78756

Mr. Melvin K. Kolzumi
Deputy Dir. for Envr. Health
1250 Punchbowl St.
P. O. Box 3378
Honolulu, HI 96801

Mr. Joe Cladouhos, Director
Div. of Envr. Health
Alaska Dept. of Envr. Conserv.
Pouch 0
Juneau, AL 99811

Mr. Jack Lilja
Envr. Health Services Section
Div. of Health, M.S. LD-11
Dept. of Social & Health Serv.
Olympia, WA 98504

Mr. Gregory J. Chakarun
Office of Envr. Health Systems
Dept. of Human Resources
1400 S.W. 5th Ave.
Portland, Oregon 97201

Mr. Douglas W. Price
Sanitary Engineering Branch
Dept. of Health Services
50 D Street, Room 205
Santa Rosa, CA 95404

SURVEY OF THE MANAGEMENT OF
STATE SHELLFISH PROGRAMS

Department of Environmental Sciences and Engineering
School of Public Health
University of North Carolina at Chapel Hill

We welcome you to the aforementioned survey and
thank you for ybur participation!

Glenda R. Lewis
Graduate Student

Dr. Morris Shiffman
Professor of Environmental Health

Do you wish to receive a summary of information submitted by all of the states responding to this questionnaire?

Yes _____ Send to: _____
 No _____

I. ORGANIZATION AND POLICY

1. Do you have a division or agency which specifically regulates shellfish? (Check appropriate response)

Yes _____ No _____

2. What specific activities or functions is each division/ agency responsible for?

<u>Function</u>	<u>Division/Agency</u>
Survey of Growing Areas	_____
Plant Inspections	_____
Patrol Activities	_____
Laboratory Analysis	_____
Resource Management (relaying)	_____

3. What is the total number of full-time staff employed within the division/agency who are responsible for the management of shellfish?

- 3a. Of this number, how many full-time staff carry out the following regulatory duties and responsibilities in managing shellfish in your state?

Growing Area Surveys	_____
Plant Inspections	_____
Patrol Activities	_____
Laboratory Analysis	_____
Resource Management	_____

II. INTERGOVERNMENTAL PROGRAM ACTIVITIES

1. Indicate frequency of contact your state has with the following federal agencies regarding shellfish management. (Please indicate with corresponding number)

very frequent	frequent	infrequent	rare	none
1	2	3	4	5
				Food & Drug Administration (FDA) _____
				National Marine Fisheries Service (NMFS) _____
				National Oceanic & Atmospheric Administration (NOAA) _____

2. Is your state currently involved or has it been involved, within the past 2 to 5 years, in interstate activities that would have an impact on shellfish growing waters? (i.e., the Chesapeake Bay Agreement of 1983)

Yes
 Currently involved _____
 Past 2-5 years _____
 No _____
 Not Applicable _____
 (for states who do
not share an estuary
 containing shellfish resources)

If Yes, please refer to the following:

2a. Which states are involved?

2b. Are the interstate activities undertaken by your state guided by written Memorandums of Understanding (MOUs), nonformalized agreement, legal agreement, or other?

MOUs _____
 Nonformalized Agreement _____
 Legal Agreement _____
 Other _____

(please indicate) _____

If No, please refer to the following:

2c. Is your state planning to become involved in interstate efforts within the next 1-2 years?

Yes _____

No _____

2d. Which of the following have you encountered as obstacles to forming interstate agreements?

Unwilling Neighboring States _____

Home State Unwilling _____

Geographical Location of _____

Home State _____

Lack of Communication Channels _____

with Neighboring States _____

Other (please indicate) _____

3. Check the following strategies which your state alone (nonregional efforts) has undertaken in the last 2 to 5 years to improve or safeguard shellfish.

Citizen Advisory Board _____

Enforcement Conferences _____

Environmental Quality _____

Standards _____

Tax Incentives _____

Civil Court Action _____

Criminal Court Action _____

Shellfish Task Force _____

None _____

Other (please list) _____

4. If your state has implemented the above strategies, how effective have they been in promoting and ensuring quality shellfish? (Please indicate below with corresponding number)

very effective	effective	neutral	ineffective	very ineffective	don't know
1	2	3	4	5	6

Citizen Advisory Board	_____
Enforcement Conferences	_____
Environmental Quality Standards	_____
Tax Incentives	_____
Civil Court Action	_____
Criminal Court Action	_____
Shellfish Task Force	_____

4a. If your state has not used these strategies, in your opinion, do you think they would be effective?

Yes _____ No _____

5. List the 3 major obstacles in managing shellfish in your state.

1) _____

2) _____

3) _____

6. What are the major factors contributing to your state developing shellfish programs? (Check all that apply)

Environmental Deterioration	_____
Concern for the Public's Health	_____
Federal/Industrial Financial	_____
Incentives	_____
State Requirements and Mandates	_____
Other (please indicate)	_____

7. Do you think a stronger or different state role is needed in managing shellfish? Or both?

Stronger role:

Yes _____
No _____

Different role:

Yes _____
No _____

Both:

Yes _____
No _____

7a. If you answered yes to any of the above, in what way should the role be altered?

III. OPERATIONS

1. Of the following, what are the measures on which your state bases its classification of waters? (Check all that apply)

Water Quality Studies _____

Pollution Source Survey _____

Hydrographic & Meteorological _____

Characteristics _____

Harvesting Practices _____

Resources (specific species _____

abundance & distribution) _____

Interrelationships of the _____

foregoing factors _____

Other (please indicate) _____

2. What is the total area (in acres) of classified shellfishing waters within your state?
- _____

2a. How much of this area (in acres) is within your division or agency's jurisdiction?

3. How many acres are prohibited? _____ Approved?
_____ Conditionally approved? _____ Restricted?
_____ Non-productive? _____ Other
classifications? (please indicate classification)

IV. PROGRAM ACTIVITIES AND FUNCTIONS

The NSSP Manual of Operations states 5 functions for states to perform in the management of shellfish:

- 1 Shoreline Surveys/Water Quality Sampling
- 2 Inspection of packing/processing plants
- 3 Laboratory Analysis
- 4 Enforcement Activities
- 5 Resource Management

The following questions pertain to activities involved in each function.

Shoreline Surveys/Water Quality Sampling

1. What method is used in conducting shoreline surveys within your state?

Desktop _____

Field _____

2. Approximately what percentage of your state's classified shellfishing waters are surveyed annually?

3. Check each of the following parameters which are included in the water quality monitoring program conducted by your division/agency.

Fecal Coliform _____

Total Coliform _____

Viruses _____

Paralytic Shellfish _____

Poisoning _____

Heavy Metals _____

Petroleum Hydrocarbons _____

Chlorinated Hydrocarbons _____

Other (Please indicate) _____

Inspection of packing/processing plants

1. What is the inspection frequency in your state?

Weekly _____

Semi-annually _____

Monthly
Quarterly

Annually
Other (Indicate
frequency)

Laboratory Analysis

1. Is growing water sampling and market sampling of shellfish meat conducted on a schedule?

Growing Water Sampling:

Yes

If yes, on what

No _____

schedule?

Market Sampling:

Yes

If yes, on what

No

schedule?

2. Do lab personnel within your division/agency follow lab procedures as delineated in the NSSP Manual of Operations or modifications of such procedures?

Manual of Operations procedures

Modifications of procedures

Enforcement Activities

1. How is harvesting controlled in your state?
(Check all that apply)

Licensing & Permitting

Identifying Closed Areas

Patrol of Growing Areas

Other (indicate method)

Resource Management

1. Who is responsible for the relaying of shellfish to another area for natural cleansing within your state? (Check all applicable)

State Patrol Agency

State Control Agency

Shellfish Industry

Depuration

1. Does your state allow depuration?

Yes _____ No _____

If Yes, please refer to the following:

- 1a. Which regulations does your state follow for depuration?

New, revised NSSP Manual _____
 Old NSSP Regulations (from _____
 NSSP 1971 Workshop) _____
 State Regulations _____

- 1b. Does your state have a schedule for the sampling of depurated shellfish?

Yes _____ If yes, on what
 No _____ schedule? _____

If No, please refer to the following:

- 1c. Why is depuration not being practised in your state?

- 1d. Is your state planning to begin depuration within the next 1 to 2 years?

Yes _____
 No _____ Why not? _____

- 1e. If yes, Why has your state decided to allow depuration?

Please include copies of any MOUs, reports, regulations and policies, or documents which would answer more concisely the items discussed above.

Thank you for your participation!

Name: _____

Title: _____

Organization: _____