

Section IX. History of the National Shellfish Sanitation Program

Introduction

The NSSP was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and State public health officials in controlling disease associated with the consumption of raw shellfish (oysters, clams, and mussels).

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of State regulatory agencies. These efforts were augmented by the assistance and advice of the Public Health Service (now the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three (3) parties combined to form a tripartite cooperative program. The guidelines of the program have evolved into the NSSP Guide for the Control of Molluscan Shellfish which is managed and updated by the Interstate Shellfish Sanitation Conference (ISSC).

Declaration of Principles

Oysters, clams, and mussels are unique foods which have been enjoyed by consumers for many years. The popularity of shellfish as a food can be traced through several centuries of American history. To early settlers, the food resources of the sea were one of the most valuable and readily usable of the natural resources, particularly from the estuaries. It is not surprising that shellfish were foremost among their staple food items.

The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use. Over 300 years ago in 1658, the Dutch Council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation, including that of New York (1715), New Jersey (1730), and Rhode Island (1734), was designed to regulate harvesting, presumably as conservation measures to guarantee a continuing supply.

Public health controls of shellfish became a national concern in the U.S. in the late nineteenth and early twentieth century when public health authorities noted a large number of illnesses associated with consuming raw oysters, clams, and mussels. These shellfish-associated outbreaks were also medically recorded in other parts of the world, most notably in European countries. During the winter of 1924, there occurred a widespread typhoid fever outbreak, with cases in New York, Chicago, and Washington, D.C., which was finally traced to sewage polluted oysters. Local and State public health officials and the shellfish industry became sufficiently alarmed over this outbreak to request that the Surgeon General of the United States Public Health Service develop necessary control measures to ensure a safe shellfish supply to the consuming public.

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

The members of the conference recommended eight (8) resolutions for the sanitary control of the oyster industry. These included:

"The beds on which shellfish are grown must be determined, inspected, and controlled by some official State agency and the U.S. Public Health Service."

"The plants in which shellfish are shucked or otherwise prepared or packed by the shipper must be inspected and controlled by some official State agency and the U.S. Public Health Service."

"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."

"The methods of shipping must be supervised, inspected, controlled and approved by the proper official Federal and State agency."

"The product must conform to an established bacterial standard and must meet Federal, State, and local laws and regulations relative to salinity, water content, and food proportion and conform to the Pure Food Laws standards."

The conference also established a committee to develop further necessary guidelines to recommend control practices for the sanitary control of the shellfish industry.

The basic concepts in formulating a program of national public health controls were reiterated by the Surgeon General in his letter of August 12, 1925, to State health officers and all others concerned. This letter set forth the following understandings:

1. The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual States; and that the requisite coordination and uniformity of control may best be achieved by mutual agreement among the States, with the assistance and cooperation of the Public Health Service..."
2. In accordance with this principle, it is considered that each producing State is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other States..."
3. In order that each State may have full information concerning the measures carried out in other States, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing State, and will report thereon for the information of the authorities of other States. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane."
4. The officers of the Public Health Service assigned to this survey work will assist the State agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable."
5. In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between State authorities."

To implement this program, the members of the 1925 conference agreed that the producing States would issue "Certificates," i.e., a permit to operate, to shellfish shippers that meet agreed upon sanitary standards. The Public Health Service would serve as a clearinghouse for information on the effectiveness of the State control programs. This clearinghouse responsibility was met initially through issuance of a periodic "Progress Report on Shellfish Sanitation" describing the shellfish sanitation program in each State. This procedure was subsequently abandoned in favor of a "program endorsement" concept. Under this concept, the Public Health Service made a continuing appraisal of each State's shellfish sanitation program to determine if the control measures were in substantial accord with the provisions of the current "Manual of Recommended Practice for Sanitary Control of the Shellfish Industry." The Public Health Service also published a list of all shellfish shippers certified by those States that maintained "satisfactory" control programs.

The procedures used by the Public Health Service in fulfillment of its obligations under the Public Health Service Act resulted from an understanding that implementation and enforcement of the necessary public health controls could best be accomplished under State laws with Federal technical support and industry participation. The National Shellfish Sanitation Program is dependent entirely upon the States adopting the recommended requirements and the cooperative and voluntary efforts of State regulatory agencies and the shellfish industry.

National Shellfish Sanitation Program

The NSSP developed from public health principles and Program controls formulated at the original conference on shellfish sanitation called by the Surgeon General of the United States Public Health Service in 1925. These fundamental components were described in a supplement to *Public Health Reports, Report of Committee on Sanitary Control of the Shellfish Industry in the United States* (Frost, 1925)

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of State regulatory agencies. These efforts were augmented by the assistance and advice of the Public Health Service (replaced by the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three (3) parties combined to form a tripartite cooperative program.

To carry out this cooperative control program, each partner accepted responsibility for certain procedures.

Each shellfish shipping State adopted adequate laws and regulations for sanitary control of the shellfish industry, completed sanitary surveys of harvest areas, delineated and patrolled restricted areas, inspected shellfish plants, and conducted such additional inspections, laboratory investigations, and control measures as were necessary to ensure that the shellfish reaching the consumer had been grown, harvested and processed in a sanitary manner. The State annually issued numbered certificates to shellfish dealers who complied with the agreed-upon sanitary standards, and forwarded copies of the interstate certificates to the Food and Drug Administration (FDA).

The FDA made an annual review of each State Shellfish Control Program including the inspection of a representative number of shellfish processing plants. On the basis of the information thus obtained, the FDA determined the degree of conformity the State Control Program had with the NSSP. For the information of health authorities and others concerned, the FDA published a monthly list of valid interstate shellfish shipper certificates.

The shellfish industry cooperated by obtaining shellfish from safe sources, by providing plants which met the agreed upon sanitary standards, by maintaining sanitary operating conditions, by placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which showed the origin and disposition of all shellfish.

Although the basic public health principles of the NSSP have remained unchanged, program procedures have been updated and improved upon at periodic intervals. The original 1925 "Report of Committee on Sanitary Control of the Shellfish Industry in the United States" was revised and reissued in 1937 and again in 1946. The document was then divided into two parts Part II entitled "Sanitation of Harvesting and Processing of Shellfish" was issued in 1957 and in 1959, Part I, "Sanitation of Shellfish Growing Areas." The need for a specialized program of this nature was reaffirmed by the cooperating members at the First National Shellfish Sanitation Workshop held in Washington, D.C., (Jensen, 1954) and at subsequent National Shellfish Sanitation Workshops (Jensen, 1956, 1958, 1961; Houser, 1964). A more complete summary of the history and evolution of the NSSP and its early approaches to resolution of shellfish sanitation issues can be found in David Clem's historical overview (Clem, 1994).

In the 1940's, the NSSP moved beyond its original 1925 objective of ensuring that shellfish shipped in interstate commerce were safe for human consumption. Paralytic Shellfish Poison (PSP) became a matter of public health concern and requirements were added to address this public health hazard. In 1957, when it was determined that shellfish could concentrate certain radionuclides, the procedures were revised to include public health controls for the pollutant. In the 1960's and 1970's, the program was again revised to address public health concern associated with heavy metals and pesticides.

Additional recommendations from the States and industry resulted in the 1965 revision of the Shellfish Sanitation Manual. This revision was prepared in cooperation with the Shellfish Control Authorities in all coastal States, food control authorities in the inland States, interested Federal agencies, Canadian Federal departments, the Oyster Institute of North America, the Pacific Coast Oyster Growers Association, and the Oyster Growers and Dealers Association of North America.

In 1968, the Sixth National Shellfish Sanitation Workshop was held (Morrison, 1969). Recommendations for further revisions to the 1965 Manual were made and accepted by Workshop participants. This Workshop was structured around twelve (12) task forces that were assigned specific topics to examine and develop recommendations for discussion by all workshop participants. This approach to examining and discussing large numbers of issues was proved successful and was recommended for use in future Workshops.

The shellfish sanitation program responsibilities assigned to the Assistant Secretary for Health, Department of Health, Education and Welfare were delegated to the Commissioner of Food and Drugs in late 1968. The FDA continued to sponsor the National Shellfish Sanitation Workshops (Ratcliffe, 1971; Wilt, 1974, 1975 and 1977). Proceedings from these Workshops contained additional recommendations for revisions to the 1965 Manual of Operations.

On June 19, 1975, the FDA proposed National Shellfish Safety Program Regulations in the *Federal Register* (FDA, 1975). There was considerable discussion at the 1975 and 1977 Workshops concerning these proposed regulations. After evaluation of the comments received as a result of the proposed rules, the FDA determined that promulgating Federal Regulations would not likely achieve NSSP goals. Subsequently, FDA decided revision of the 1965 Manual of Operations was the best approach for strengthening the NSSP. (See Federal Register of February 26, 1985, 50 F.R. 7797)

During this period, many Authorities began questioning the uniformity and effectiveness of shellfish programs in other States. These States and FDA began exploring methods for strengthening the NSSP that would not involve Federal regulations. In reviewing other approaches, it was noted that since 1950 the National Conference of Interstate Milk Shippers (NCIMS), a successful voluntary public health program, has been successful in assuring a nationwide safe and wholesome milk supply. The NCIMS was consulted for direction and advice.

The success of the NCIMS program prompted State shellfish control officials and FDA to select the NCIMS program as a model for developing a shellfish organization. In 1982, a delegation of State officials from 22 States met in Annapolis, Maryland and formed the Interstate Shellfish Sanitation Conference (ISSC). The ISSC is composed of State shellfish regulatory officials, industry officials, FDA, and other Federal agencies.

The ISSC organization provides the forum for State regulatory officials to establish uniform National guidelines and to exchange information regarding sources of safe shellfish. The first annual meeting was held in New Orleans, Louisiana in August 1983. At this conference, the ISSC adopted the 1965 NSSP Manuals of Operation, as well as formal procedures for adopting changes to the Manuals. These documents provided the basis for an Interstate Shellfish Sanitation Program (ISSP). In March 1984, FDA entered into a Memorandum of Understanding (MOU) with the ISSC. The MOU formalized the FDA's relationship with the ISSC and established the ISSC as a Federal-State-industry cooperative body. The ISSP, acknowledged in the 1984 MOU, is a set of guidelines for the sanitary control of shellfish, adequate to ensure that shellfish will be safe and sanitary.

At its second annual meeting in Orlando, Florida in August 1984, the ISSC accepted for review a revision of Part I of the 1965 NSSP Manual of Operations. At the third annual meeting in Cherry Hill, New Jersey, in August, 1985, the ISSC adopted an updated Part I of the NSSP Manual of Operations (published in 1986), and accepted for review a revision of Part II of the 1965 NSSP Manual. In preparing the draft revision of the 1965 NSSP Manual of Operations, FDA relied principally on the following sources:

1. The draft revision of the Proposed National Shellfish Safety Program Regulations, Part 951;
2. The 1965 NSSP *Manual of Operations, Part I, Sanitation of Growing Waters; Part II, Sanitation of the Harvesting and Processing of Shellfish; and Part III, Appraisal of State Shellfish Sanitation Programs*, U.S. Department of Health, Education, and Welfare, Public Health Service Publication No. 33;
3. The National Shellfish Sanitation Program Workshop Proceedings for 1968, 1971, 1973, 1974, and 1977;
4. The Environmental Protection Agency rules and regulations (40 CFR Parts 400, et seq.) concerning water pollution control and shellfish waters;
5. Other Federal laws and regulations concerning quality of shellfish and shellfish growing areas;
6. Existing State rules and regulations concerning shellfish growing area control and water quality criteria;
7. Analytical methods accepted by the American Public Health Association, Association of Official Analytical Chemists, American Society of Testing Materials, and other voluntary standard-setting organizations relating to shellfish and shellfish waters; and
8. Recommendations from the Interstate Shellfish Sanitation Conference.

Developing the updated Manual was a cooperative effort between FDA and the ISSC. Initial drafts were prepared by FDA and presented to the ISSC and other interested parties for review and comment.

Comments were incorporated into drafts after consultation with the ISSC, and the final revision was presented to the ISSC for formal endorsement in 1986. In updating the 1965 Manual, the harvesting and the processing of shellfish continued to be recognized as two (2) distinct phases of operation in the shellfish industry. Therefore, the updated Manual was published in two parts; Part I: *Sanitation of Shellfish Growing Areas* (1986); and Part II: *Sanitation of the Harvesting, Processing and Distribution of Shellfish* (1987). Part I of the Manual continued as a guide for preparing State shellfish laws and regulations pertaining to sanitary control of shellfish harvest area classification, laboratory procedures, relaying, patrol operations and marine biotoxin. Part II of the Manual continued as a guide for operating, inspecting and certifying shellfish shippers, processors and depuration facilities; and for controlling interstate shipments of shellfish. Part III: *Public Health Service Appraisal of State Shellfish Sanitation Programs* was discontinued by the FDA.

In addition to setting forth the principles and requirements for the sanitary control of shellfish produced and shipped in interstate commerce in the U.S., the updated Manual was intended to be used by the States to control the harvesting and handling of shellfish for recreational and intrastate commercial use. Most coastal States believe that consumers residing in their State should be provided equal public health protection, as are consumers in other States under the interstate certification program. To accomplish this, States may apply the same water quality and harvesting restrictions on non-interstate shellfish activities as on interstate activities. Having uniform intra and interstate programs also greatly facilitates the effective implementation and regulation of all shellfish harvesting activities, and results in the most efficient utilization of public health resources.

The updated Manual was also to be used by FDA as the basis for evaluating foreign shellfish sanitation programs. To accomplish this, FDA seeks to establish international MOUs with official agencies in those foreign countries that wish to export shellfish to the U.S. An MOU is established after the foreign government demonstrates to FDA that the government has laws or regulations equivalent to those published in the Manual, and that the foreign program was supported by trained personnel, laboratory facilities, and other resources as may be necessary to exercise control over the export shellfish industry. Once a country has an effective MOU, the Shellfish Control Authority submits certificates of their certified shellfish dealers to the FDA. The FDA publishes the names of these certified shellfish shippers in the Interstate Certified Shellfish Shippers List (ICSSL) as an approved source of shellfish.

In the years 1986 through 1995, under its 1984 MOU with the Interstate Shellfish Sanitation Conference (ISSC), the FDA published seven revisions of the Manual. Between 1995 and 2003, the ISSC/FDA has published two (2) revisions of the NSSP Guide for the Control of Molluscan Shellfish. The revisions were the result of the findings and recommendations from the annual meetings of the ISSC and reflected mutual FDA and ISSC concurrence. A full listing of all editions of the Manual of Operations for the NSSP can be found in the reference portion of this section.

The intent in establishing the ISSP Program was to modify the Manuals into a model ordinance format and include the ordinance with other shellfish related documents and procedures into an ISSP Handbook.

Interstate Shellfish Sanitation Program

During development of the ISSC, FDA, State regulatory officials, and the industry worked diligently to establish uniform guidelines and to exchange reliable information on sources of safe shellfish, and to provide revisions to the NSSP Manual as necessary through formal ISSC procedures. These efforts have been conducted under the umbrella of the March 1984 MOU between the FDA and the ISSC. The

Memorandum formally established an FDA cooperative relationship with both the States and shellfish industry. The ISSC continues to play an important role in assuring that uniform shellfish control measures are adopted, and that those measures are enforced consistently by State regulatory authorities.

One of the foremost goals of the ISSC has been the adoption of a Model Ordinance which would embody the principles and requirements of the ISSP. Adoption of the Model Ordinance by each of the ISSC participating States implies commitment by each State to provide the necessary legal authority and resources to implement these regulatory requirements. Adoption also ensures uniformity across State boundaries and enhances public confidence in shellfish product.

Development of the Model Ordinance began in 1987 with the establishment of the ISSC Model Ordinance Committee, which included representatives of the FDA, the States and the industry. The Model Ordinance Committee worked to incorporate the NSSP Manual into the format of regulation and to resolve inconsistencies within the Manual. The initial draft Ordinance was presented to and adopted by the ISSC at its 1992 meeting. The FDA responded with comments and requested development of a strategy for the transition from the NSSP Manual to the Model Ordinance as the basis for the NSSP and for use by FDA in reviewing State Shellfish Sanitation Programs.

The ISSC recognized the importance of retaining many of the elements of the NSSP Manual that should not be incorporated into an ordinance. To accomplish this, the Model Ordinance Committee recommended development of the Interstate Shellfish Sanitation Program Handbook which would include, in addition to the Model Ordinance, guidance documents concerning important components of the NSSP, references, public health reasons for NSSP requirements, and procedures which support or are used in the NSSP. The ISSC Constitution, By-laws and Procedures were revised to recognize an Interstate Shellfish Sanitation Program (ISSP) and its Model Ordinance as replacing the NSSP on January 1, 1998, as the effective rules governing participation in the ISSC. However, further discussions by the ISSC Executive Board and FDA regarding recognition and identify of the Program have resulted in retention of the National Shellfish Sanitation Program title hereafter referred to as the NSSP.

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