

Interstate Shellfish Sanitation Conference



Constitution, Bylaws, and Procedures

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PREFACE

The sanitary quality of shellfish shipped interstate as well as intrastate has been a matter of concern to receiving areas for many years. The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wide use. In 1658, the Dutch Council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation (1715, 1730, and 1734) was designed to regulate harvesting, presumably as conservative measures to guarantee a continuing supply.

The public health problems which were associated with shellfish in the United States in the first two decades of the twentieth century brought a new dimension to natural resource utilization; i.e., shellfish could not be used as food unless of acceptable sanitary quality. The concept was clearly recognized in a Public Health Service sponsored conference in 1925. All parties seemed to recognize and accept as fact, the premises that: (1) shellfish represented a valuable natural food resource; (2) the cultivation, harvesting, and marketing of this food resource were valuable to the economy of many coastal communities; (3) a state/federal program was necessary to permit the safe use of this resource; and (4) the transmission of disease by shellfish was preventable and, therefore, not to be tolerated. Founders of the shellfish program held that instead of prohibiting use of this resource, beneficial use of the estuaries was in the best public interest, and that sanitary controls should be developed and maintained which would allow safe use.

In 1954, the Surgeon General of the United States Public Health Service called a second national conference to discuss shellfish sanitation problems. There was general agreement that, despite the profusion of technical problems, the basic concepts were sound and that it was in the public interest to maintain the program. The 1964 National Shellfish Sanitation workshop stated that survival of the shellfish industry was in the best public interest and that application of the established principles on a state-by-state basis would allow shellfish to continue to be used safely as food.

In the ensuing years, changes in the state and federal governmental organizations participating in the shellfish program and challenges to portions of the federal part of the program made participation in the program by state regulatory officials and the shellfish industry less effective. Various state programs began to diverge from established standards and the federal arm of the program appeared to be unable to retain control or re-establish uniform program application necessary to ensure the safety of shellfish for use as food. As a result, representatives of fifteen shellfish producing states met in Ocean City, Maryland, in October 1979 to investigate the problem.

This meeting established a committee to explore the alternative types of organizations that could deal with the problems and continue to ensure a viable, uniform national program. The committee, after two years of serious deliberations and numerous meetings, developed a proposal for an organization of state shellfish regulatory and industry representatives interfacing with the United States Food and Drug Administration to establish uniform basic guidelines that could be used for sanitary control of the shellfish industry. The recommended program of this proposed organization would provide regulatory authorities with reliable data on sources of high quality shellfish. The recommended

program could also be used to advantage by states and municipalities in developing sound, uniform programs to secure better shellfish supplies for their people.

In the following year the committee held meetings with representatives of the FDA, industry, and various states and further refined the proposal. A final draft was prepared and notice of a national meeting to present the proposal to state shellfish control officials for adoption was mailed.

A national meeting was convened in Annapolis, Maryland, on September 20, 1982. Representatives attended the meeting from twenty-two states, shellfish industry representatives from several east and Gulf Coast states, the United States Food and Drug Administration, and the National Marine Fisheries Service. Consideration and amendment of the Committee Proposal resulted in adoption of a Constitution, By-Laws, and Procedures on September 21, 1982, establishing a viable organization with the stated purpose of fostering and improving the sanitation of shellfish through interstate cooperation and through uniformity of state shellfish programs.

DEFINITIONS

The following definitions apply to the Constitution, By-Laws, and Procedures of the Interstate Shellfish Sanitation Conference.

- (1) **INDUSTRY** - any commercial operation routinely dealing in the harvesting, processing, packaging, storage, or distribution of shellfish.
- (2) **INTERPRETATION** - a written request for a clarification of a part of the National Shellfish Sanitation Program from the FDA Regional Office to FDA Headquarters, and the written response to that request from FDA Headquarters.
- (3) **ISSC REGION** - geographical grouping of shellfish producing states with similar characteristics and interests, established to provide for fairly distributed representation. The ISSC Regions shall be:
 - Region 1 - Maine, New Hampshire, Massachusetts, Rhode Island
 - Region 2 - Connecticut, New York, New Jersey
 - Region 3 - Maryland, Delaware, Virginia
 - Region 4 - North Carolina, South Carolina, Georgia, Florida
 - Region 5 - Alabama, Mississippi, Louisiana, Texas
 - Region 6 - Alaska, Washington, Oregon, California, Hawaii
- (4) **NATIONAL SHELLFISH SANITATION PROGRAM (NSSP)** - the cooperative State-FDA-Industry program for the sanitary control of shellfish. Cooperative partners may include States, the FDA, industry, tribes, other nations, and other federal agencies. The Guide for the Control of Molluscan Shellfish, including the Model Ordinance as adopted by the Interstate Shellfish Sanitation Conference replaced the NSSP Manual of Operations [effective January 1, 1998] and contains the same requirements in ordinance language.
- (5) **NON-PRODUCING STATE** - any state that does not qualify as a producing state.
- (6) **PARTICIPATING MEMBER** - any individual wishing to participate or receive correspondence from the Conference.
- (7) **PRODUCING STATE** - a state having shellfish growing waters in its jurisdiction and having certified shellfish plants for the initial processing of shellfish.
- (8) **REGISTERED VOTE** - (as used in Article XI. Section 3.b.) the maximum possible vote during the current Conference meeting, determined by counting the votes or portions of votes of all registered voting delegates.
- (9) **SHELLFISH** - means all species of:
 - (a) Oysters, clams or mussels, whether:
 - (i) Shucked or in the shell;

- (ii) Raw, including post harvest processed;
 - (iii) Frozen or unfrozen;
 - (iii) Whole or in part; and
 - (b) Scallops in any form, except when the final product form is the adductor muscle only.
- (10) **STATE** - a shellfish producing or receiving state that participates and votes in the Conference General Assembly.
- (11) **STATE SHELLFISH CONTROL AUTHORITY (SSCA)** - the state agency or agencies having the legal authority to classify shellfish growing waters, to issue certificates for the interstate shipment of shellfish and to regulate harvesting, processing and shipping in accordance with the NSSP Model Ordinance [effective January 1, 1998].
- (12) **UNRESOLVED ISSUE** - a disagreement or continued failure to achieve satisfactory compliance with the NSSP Model Ordinance. Unresolved issues may be between FDA and a state or between states or non-state parties.
- (13) **VOTING DELEGATE** - the person designated by a state shellfish control authority to cast the agency's portion of the state vote in Conference meetings.

CONSTITUTION
OF THE
INTERSTATE SHELLFISH SANITATION CONFERENCE

ARTICLE I. ORGANIZATION

- Section 1.** The name of the organization shall be the "Interstate Shellfish Sanitation Conference", hereinafter referred to as the Conference.
- Section 2.** The Conference shall be directed by and shall be under the control of the various states, federal agencies and shellfish industry that join together to form the Conference.

ARTICLE II. OBJECTIVES

- Section 1.** The objective of the Conference shall be to foster and improve the sanitation of shellfish in this country and to encourage restoration of shellfish growing areas.
- Section 2.** The objective of the Conference shall be accomplished by:
- Subdivision a. Adopting sound, uniform methods into a National Shellfish Sanitation Program that is accepted by participating shellfish control authorities.
- Subdivision b. Promoting mutual respect and trust among shellfish control authorities, the shellfish industry, and consumers of shellfish.
- Subdivision c. Acquainting control authorities, producers, processors, and consumers with the purpose of the Conference through the media of meetings, press releases, and publications, and by utilization of facilities and personnel of educational institutions, trade associations, shellfish control authorities, and other groups that are willing to assist in the dissemination of such information.

ARTICLE III. REGISTRATION AND FEES

- Section 1.** Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.
- Section 2.** Persons attending and participating in a Conference meeting must first register their name, address, and affiliation with the Executive Director and pay the appropriate registration fee.
- Section 3.** Registration fees shall include those amounts required by Article V., Section 9. of this Constitution.

Section 4. There shall be two (2) categories of membership:

Subdivision a. State
Subdivision i. Shellfish producing states
Subdivision ii. Non-producing states

Subdivision b. Individual Member

The fee for each category of membership and the membership period shall be set by the Executive Board. The membership fees may be paid annually or biennially. The state authority membership dues shall include membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee. The membership period shall coincide with the calendar year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

Section 1. The Conference shall elect its Executive Board, hereinafter called the Board, in accordance with Article IV. Sections 2, 6, and 7 of this Constitution.

Section 2. The Board shall be comprised of eighteen (18) voting members selected as follows: (a) six (6) state shellfish control authority members elected from the producing states, one (1) from each of the ISSC Regions; (b) three (3) state shellfish control authority members elected at large from the non-producing states; (c) six (6) members elected from industry, one (1) from each of the ISSC Regions; (d) one (1) member designated by the United States Food and Drug Administration; (e) one (1) member designated by the National Marine Fisheries Service; and (f) one (1) member designated by the United States Environmental Protection Agency.

Section 3. The immediate past Chairperson, the Program Chairperson, the three (3) Task Force Chairpersons, the Executive Director, and the Biennial Meeting Office Manager, except as otherwise provided, shall serve as non-voting members of the Board.

Section 4. The Treaty Tribes of Western Washington, signatory to the Consent Decree regarding shellfish sanitation with the State of Washington, shall have a non-voting member on the Executive Board designated by the tribal parties to the Consent Decree, whose name shall be submitted by the Northwest Indian Fisheries Commission.

Section 5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative. The Consumer Advisor shall serve a two (2) year term. The initial Consumer Advisory term shall be one (1) year to coincide with the Biennial meeting schedule.

- Section 6.** Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.
- Section 7.** Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Biennial Conference meeting.
- Section 8.** The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Biennial Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.
- Section 9.** The Executive Committee, at a minimum, shall consist of the Board Chairperson, Vice Chairperson, Office Manager, Program Chairperson, one Industry Executive Board member, and the immediate past Board Chairperson. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. Industry representation on the Executive Committee shall be appointed by the Chairperson of the Executive Board, at each Biennial Meeting, with recommendation from the industry members of the Board.
- Section 10.** The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairman. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: Education, Foreign Relations, Proposal Review, Patrol, Research Guidance, Resolutions, and Shellfish Restoration. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.
- Section 11.** A quorum for conducting Board business shall consist of ten (10) voting members.
- Section 12.** The nine-member Unresolved Issues Committee shall be comprised of a state regulatory representative from each of the six (6) regions, one (1) state regulatory representative from a non-producing state, and two (2) industry representatives at large. Should a state regulatory committee member be a representative from a state affected by an unresolved issue, the ISSC Board Chairperson shall appoint a substitute representative from another state within the same region or another non-producing state. Should an industry committee member be a representative from a state affected by an unresolved issue, the ISSC Board Chairperson shall appoint a

substitute at-large industry representative. The committee Chairperson shall be a non-voting member except in the event of a tie.

Section 13. The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson and four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and prioritize proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.

ARTICLE V. DUTIES OF THE BOARD

Section 1. The Board shall manage the affairs of the Conference. The Board may act on behalf of the Voting Delegates between voting Conference meetings, in keeping with the spirit and intent of the delegates. Any decision or action taken by the Board which would require Voting Delegate approval in accordance with the remainder of this Constitution, By-Laws, or Procedures, shall be submitted as a proposal to the next voting meeting for concurrence or correction.

Section 2. The Board shall meet during each Conference meeting and after the voting General Assembly of the regular Biennial Conference meeting. The Board Chairperson shall call special meetings of the Board at any time at the request of two-thirds (2/3) of its members. The Board Chairperson may call special meetings of the Board at any time, as the need arises, with the concurrence of two-thirds (2/3) of the Board members.

Section 3. The Board may retain the services of an Executive Director who shall serve as chief administrator of the Conference.

Section 4. The Board shall direct the Executive Director and the Program Chairperson in the preparation of programs for each General Assembly of the Biennial Conference meeting.

Section 5. The Board shall set the time and place of each required Biennial Meeting of the Conference. Special meetings of the Conference may be called as the need arises.

Section 6. In the event a vacancy occurs in its membership between elections, the Board may fill such vacancy with a qualified Conference member from the area represented to serve the unexpired term.

Section 7. If a member of the Board is unable to attend a meeting, he/she may send an elected alternate. The member shall notify the Executive Director of the substitution prior to the meeting and provide the substitute with a letter of proxy. In the event time or circumstances prevent prior notification of the alternate to the Executive Director, the letter of proxy presented to the Executive Director at the meeting shall be sufficient.

Section 8. A Board member who fails to attend two (2) consecutive Board meetings shall show cause why he/she should not resign and his/her position be declared vacant by the Executive Director. The Board meeting during each Conference meeting and the Board meeting immediately after the voting general assembly of the regular Biennial Conference meeting shall be considered as one meeting for the purposes of this Section.

Section 9. The Board shall direct the Executive Director to collect membership and registration fees as necessary to defray the costs of the meeting and operation of the Conference. The Executive Director shall pay all bills approved by the Board. The registration fee amount shall be set by the Board. The Board shall cause an audit to be made of the Executive Director's financial report annually. The Board shall direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Biennial Meeting.

Section 10. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings.

Section 11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership at each Biennial Meeting.

ARTICLE VI. DUTIES OF THE BOARD CHAIRPERSON

Section 1. The Board Chairperson shall preside at all meetings of the Board and during Conference meetings, except as provided for in Article VII. of this Constitution.

Section 2. The Board Chairperson, with the approval of the Board, shall appoint committees as directed by the Conference, the Board, the Constitution, or the By-Laws.

Section 3. The Board Chairperson, with the approval of the Board, shall appoint the Task Force Chairpersons, Vice-Chairpersons, and Members as outlined in Article I., Section 2. and Section 3. of the By-Laws of the Conference.

Section 4. The Board Chairperson, with the approval of the Board, shall appoint Task Force consultants as outlined in Article II. Section 1. of the By-Laws of the Conference.

Section 5. The Board Chairperson, with the approval of the Board, shall appoint a Program Chairperson and a Biennial Meeting Office Manager.

Section 6. The Board Chairperson, with the approval of the Board, shall appoint an Unresolved Issues Committee.

Section 7. The Board Chairperson, with the approval of the Board, shall appoint Executive Board advisors.

ARTICLE VII. DUTIES OF THE VICE-CHAIRPERSON

Section 1. In the event the Board Chairperson is unable to attend any meeting of the Board or Conference, the Board Vice-Chairperson shall act as Board Chairperson at the meeting.

Section 2. When acting as Board Chairperson as provided in Section 1. of this Article, the Vice-Chairperson shall perform all the necessary duties for the Conference as outlined in Article VI. of this Constitution.

ARTICLE VIII. DUTIES OF THE EXECUTIVE DIRECTOR

Section 1. The Executive Director shall serve as chief administrator of the Conference and shall serve as a non-voting member of the Executive Board. The Executive Director shall conduct the affairs of the Conference and shall implement the decisions and policies of the Board and voting delegates.

Section 2. The duties of the Executive Director shall be:

Subdivision a. Coordination of ISSC external affairs, specifically interacting with other designated organizations, federal and State government agencies, Congressional committees and staff, State legislative bodies, shellfish and other food-related industries, and other entities whose work or interests affect public health issues relating to the consumption of molluscan shellfish;

Subdivision b. Advisement of the Board concerning prioritization of external areas requiring ISSC involvement. Assistance in development of long-range goals and strategies;

Subdivision c. Preparation and oversight of position papers or other public policy documents for approval by the Board. Preparation of routine ISSC correspondence;

Subdivision d. Spokesperson for ISSC providing or arranging testimony or dialogue on ISSC issues and positions;

Subdivision e. Management of the Executive Office and supervision of Executive Office staff;

Subdivision f. Management of the fiscal affairs of ISSC in cooperation with the Executive Committee.

Section 3. The Executive Director shall plan and arrange all Conference meetings.

Section 4. The Executive Director may retain the services of a parliamentarian to rule on matters of parliamentary procedure at Board meetings and during Conference meetings.

- Section 5.** The Executive Director, with the approval of the Board, may retain clerical assistance as needed.
- Section 6.** The Executive Director shall record the minutes of each meeting of the Board and the Conference.
- Section 7.** The Executive Director shall tally and record all voting of the Board and of the Conference on a form authorized by the Board.
- Section 8.** The Executive Director shall pay bills as directed by the Board. A receipt shall be obtained for all disbursements and shall be made a part of Board records.
- Section 9.** The Executive Director shall accomplish the requirements outlined in Article XI, Section 3.d., Section 3.e., Section 3.f., and Section 3.g. of this Constitution.
- Section 10.** The Executive Director shall mail a copy of the tentative program sixty (60) days prior to the Conference meeting to each registrant of the previous Conference meeting and to any State authority or shellfish industry member or representative who so requests and shall prepare and distribute programs at each Conference meeting.
- Section 11.** The Executive Director shall notify the appropriate shellfish control authorities in each state, at least ninety (90) days prior to each Conference meeting, of the time and place of the meeting and what proposals are to be voted on under the heading of unfinished business.
- Section 12.** The Executive Director shall notify the United States Food and Drug Administration, National Marine Fisheries Service, and the United States Environmental Protection Agency at least one hundred twenty (120) days prior to each Conference meeting of the time and place of the meeting so that FDA can publish this information in the Interstate Shellfish Shippers List (ICSSL) at least ninety (90) days prior to the meeting.

ARTICLE IX. DUTIES OF THE PROGRAM CHAIRPERSON

- Section 1.** The Program Chairperson shall assist the Executive Director in planning and arranging for all Conference meetings.
- Section 2.** The Program Chairperson shall serve as a non-voting member of the Executive Board.

ARTICLE X. DUTIES OF BIENNIAL MEETING OFFICE MANAGER

- Section 1.** The Biennial Meeting Office Manager shall assist the Executive Director in planning, establishing, and managing the operations center for the Biennial Meeting.

Section 2. The Biennial Meeting Office Manager shall serve as a non-voting member of the Executive Board.

ARTICLE XI. RULES OF BIENNIAL CONFERENCE MEETINGS

Section 1. Except for special meetings, as provided for in Article V., Section 5. of this Constitution, the Conference will convene a meeting annually through 1999 and biennially during the odd numbered years thereafter and will rotate it among the different Regions of the country.

Section 2. Conference meetings shall include the following:

Subdivision a. Registration - all attendees must register;

Subdivision b. Call to order by the Board Chairperson;

Subdivision c. Roll call of the states and announcement of the name of the delegates who will vote for each state in General Assembly;

Subdivision d. Audit report;

Subdivision e. Unfinished business;

Subdivision f. Subcommittee and Committee meeting;

Subdivision g. Task Force meetings;

Subdivision h. Election of Board members;

Subdivision i. Program, new business, and committee reports;

Subdivision k. Installation of new Board members;

Section 3. Business Rules of Conference Meetings

Subdivision a. Robert's Rules of Order shall prevail, unless specific rules are established by the Conference.

Subdivision b. Each shellfish producing state shall be entitled to one (1) full vote in the Conference meeting general assembly and each non-producing state shall be entitled to one (1) vote in the Conference meeting general assembly with the exception of issues involving Task Force I recommendations. Non-producing states shall be entitled to one-half (1/2) vote on proposals involving Task Force I recommendations. In states where elements of the NSSP are administered by different shellfish control agencies, each agency shall have an appropriate portion of the vote, or at the option of the state, the vote may be combined and cast by the voting delegate of the single shellfish control agency selected by the state. Membership fees must be paid by the participating state in order to exercise voting privileges.

Subdivision c. Only a registrant at the Conference meeting who is a representative of a state shellfish control authority is entitled to be a voting delegate. Each voting delegate at the meeting may cast a vote only for his/her own state agency, except when the state vote has been combined in accordance with Article XI. Section 3.b. of this Constitution and assigned to his/her agency.

Subdivision d. Ninety (90) days prior to a meeting, the Executive Director shall send to the office or offices of all appropriate shellfish control authorities in each participating state notice of the forthcoming meeting. Each notice shall include a copy of Article XI. Section 3.b., Section 3.c., and Section 3.d. of this Constitution. Each authority shall report in writing on forms provided within thirty (30) days to the Executive Director the following: (1) its official designated responsibility, (2) the name of the delegate and alternate or alternates and the agency represented, and (3) the portion of the vote the delegate is to cast.

Subdivision e. In the event the sum total of the portions of the vote designated for an individual state's delegates exceeds the amount authorized for that state, the Executive Director shall reject, void, and return the reports to the authorities for correction so that they are in compliance with Article XI. Section 3.b. of this Constitution. Such revision shall be submitted at least thirty (30) days before the meeting.

Subdivision f. A qualified Voting Delegate who must leave the meeting may transfer his/her voting privileges to another qualified registrant from his/her state. The transfer must be presented in writing to the Credentials Committee signed by the departing voting delegate. Upon approval, the Credentials Committee Chairperson shall notify the Executive Director of the transfer of voting privilege.

Subdivision g. Each state Voting Delegate shall record his/her name with the Executive Director and shall cast his/her vote in the Conference meeting General Assembly when the state's name is called by announcing "yes" or "no" for the delegate's appropriate portion of the vote.

Subdivision h. Voting in the Conference meeting General Assembly shall be recorded as "yes" or "no".

Subdivision i. In case of a roll call vote, if a state's representative wishes to caucus, the delegates may pass for the purpose of caucusing when the state's name is called and then shall vote when the second roll is called.

Subdivision j. To adopt in Conference meeting general assembly:

Subdivision i. A quorum must be present.

Subdivision ii. A quorum shall consist of two-thirds (2/3) of the registered vote at the Conference meeting.

Subdivision iii. In order to adopt a new Procedure, a simple majority vote is required for passage. In order to change an existing Procedure in any way, a two-thirds (2/3) majority vote is required for passage.

Subdivision k. Recommendations from a Task Force can be adopted as written, editorially amended to be correct, or consistent with other language in the NSSP Model Ordinance, Constitution, By-Laws, or

Procedures, rejected by voting "No Action", or referred back to a Task Force or Committee. The Executive Director will determine whether it is referred to a Task Force or Committee.

ARTICLE XII. AMENDMENTS

Section 1. This Constitution may be amended at a duly called Conference meeting, the delegates having had sixty (60) days notice from the Executive Director of proposed amendments. Adoption of an amendment to the Constitution shall require at least a two-thirds (2/3) majority vote.

Section 2. Amendments to the Constitution will become effective at the close of the Conference meeting at which they are adopted.

ARTICLE XIII. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

Section 1. The Executive Director shall provide each registrant of the preceding Conference meeting at least one hundred sixty-five (165) days prior to the next Conference meeting with forms on which proposal for problems are to be submitted to the Executive Director for assignment to the appropriate Task Force.

Section 2. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting.

Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force.

Section 4. The Executive Director shall review and assign all problems or proposals received for Task Force and Conference deliberation. Problem or proposal assignment shall be made according to subject matter and in accordance with Article XIII. Section 5., Section 6., and Section 7. of the Constitution of the Conference.

Section 5. Task Force I - Growing Areas: all proposals submitted to the Conference dealing with the classification or patrol of shellfish growing waters, relaying, training and research, or similar items concerning growing areas shall be assigned to Task Force I by the Executive Director.

Section 6. Task Force II – Harvesting, Handling, and Distribution: all proposals submitted to the Conference dealing with the sanitation of harvesting, depuration, processing, labeling, transporting, storage, fill or content, training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director.

Section 7. Task Force III - Administration: all proposals submitted to the Conference dealing with Conference agreements, memorandums of understanding, complaints and challenges of reciprocity and program evaluations, or similar items, or items not

specifically relating to Task Force I or II shall be assigned to Task Force III by the Executive Director.

Section 8. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business.

Section 9. Proposals submitted after the deadline, established in Article XIII Section 2 of the Constitution, will be reviewed and may be accepted by the Executive Board for Task Force Consideration. The Executive Board will use the following criteria in accepting late proposals.

Subdivision a. Why is the proposal being submitted after the deadline?

Subdivision b. Was the information available prior to the deadline?

Subdivision c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC?

Subdivision d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change?

Section 10. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.

Section 11. The Proposal Review Committee will review and prioritize proposals for Task Force consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.

BY-LAWS
OF THE
INTERSTATE SHELLFISH SANITATION CONFERENCE

ARTICLE I. TASK FORCES

Section 1. There shall exist three (3) Task Forces in the Conference to provide for continuity of action in carrying out the objectives of the Conference. The Task Forces shall be known as Task Force I, Task Force II, and Task Force III.

Section 2. Each Task Force shall have a total voting membership of eight (8) members to be appointed by the Board Chairperson with the approval of the Board.

Subdivision a. Four (4) of the voting members shall be selected from state shellfish control authorities and four (4) shall be selected from industry providing that each ISSC Region shall be represented by at least one (1) Task Force member, either industry or regulatory. The Chairperson (the ninth voting member who will vote only in case of a tie vote) shall alternately be selected from a state shellfish control authority and from industry as outlined in Article I., Section 3. of the By-Laws.

Subdivision b. Three (3) of the state shellfish control authority members shall be from producing states and one (1) shall be from a non-producing state, except for Task Force I where at least four (4) shellfish control authority members shall be from producing states. Prior to the March Board meeting, the industry and regulatory Board member from each region may submit a list of Task Force nominees of up to three (3) candidates each per Task Force to the Board Chairperson. The Board Chairperson shall appoint a member from each ISSC Region to each Task Force from the list of candidates submitted. The Board shall approve the candidates selected. In the absence of any nominees submitted from a region, the Board Chairperson, with Board approval, shall appoint the Task Force member.

Section 3. The Board Chairperson, with approval of the Board, shall appoint a Chairperson and Vice-Chairperson for each Task Force.

Subdivision a. If the Task Force Chairperson represents a state shellfish control, the Vice-Chairperson shall be an industry representative.

Subdivision b. At the end of the Task Force Chairperson's term of office, the Vice-Chairperson will become Chairperson and a new Vice-Chairperson will be appointed who represents the same segment of the Conference as the outgoing Task Force Chairperson.

Section 4. The Task Force Chairperson and Vice-Chairperson shall serve for a four (4) year period, i.e., through two (2) consecutive Conference Biennial meetings. Task Force members may not serve more than two (2) consecutive Biennial Meetings on the same Task Force.

Section 5. A quorum for conducting Task Force business shall consist of five (5) voting members.

Section 6. Each Task Force shall deliberate all proposals during the times specified at the Conference meeting. Each Task Force Chairperson shall report the actions recommended by his/her respective Task Force to the voting delegates at the Conference under the heading of New Business for final Conference consideration. Any "No Action" recommended by a Task Force shall contain the reasons for the "No Action" recommendation.

Section 7. If a Task Force member is unable to attend the Biennial Meeting, he/she shall notify the Executive Director prior to the first Executive Board meeting. The Board Chairperson, with approval of the Board, shall appoint a replacement that represents the same segment of the Conference as the member who is unable to attend to serve the remainder of the unexpired term. The Board Chairperson will confer with Board members from the affected region before appointing a replacement.

ARTICLE II. TASK FORCE CONSULTANT

Section 1. The Board Chairperson shall appoint a consultant for each Task Force from the Board.

Section 2. FDA and NMFS may provide a consultant for each Task Force.

Section 3. Consultants will have no voting rights in Task Force action but will attend Task Force deliberations to offer advice as needed.

ARTICLE III. AMENDMENTS

Section 1. These By-Laws may be amended at a duly called Conference meeting, the Delegates having had sixty (60) days notice from the Executive Director of proposed amendments. Adoption of an amendment to the By-Laws shall require at least a two-thirds (2/3) majority vote.

Section 2. Amendments to the By-Laws will become effective at the close of the Conference meeting at which they are adopted.

PROCEDURES
OF THE
INTERSTATE SHELLFISH SANITATION CONFERENCE

PROCEDURE I. PURPOSE

The Interstate Shellfish Sanitation Conference (ISSC) is intended to foster and improve the sanitation of shellfish through cooperation and through uniformity of state shellfish programs.

PROCEDURE II. PROGRAM

Section 1. To achieve its goal, the ISSC will adopt a NSSP Guide for the Control of Molluscan Shellfish for sanitary control of shellfish that is adequate to ensure that the shellfish produced in a state that complies with these guidelines will be safe and sanitary. This NSSP Guide for the Control of Molluscan Shellfish shall be called the National Shellfish Sanitation Program (NSSP).

Section 2. The ISSC shall adopt an NSSP Guide for the Control of Molluscan Shellfish as the NSSP, effective January 1998.

PROCEDURE III. RESPONSIBILITIES OF THE STATE

Section 1. The state shall have adequate laws and regulations to provide a legal basis for sanitary control of all interstate phases of the shellfish industry.

Section 2. The state shellfish growing area classification authority shall forward the classification of shellfish growing waters in the state to the appropriate Food and Drug Administration (FDA) Regional Office. The most recent classification shall be reported. When the classification of growing waters changes, the most recent classification shall apply and shall be submitted to FDA. The state shellfish growing area classification authority shall keep current the classification of all growing waters within its state.

Section 3. The state shellfish sanitation control authority of the shipping state shall certify the results of inspections of each interstate shellfish shipper meeting NSSP requirements to the FDA headquarters office for inclusion in the Interstate Certified Shellfish Shippers List (ICSSL), with copies to the appropriate FDA Regional Office. The certification inspection report, together with other pertinent information, shall be forwarded with the appropriate FDA form number FDA 3038b. The most recent certification status of a shipper shall be reported. When the sanitation compliance status of a listed shipper changes, as a result of a new inspection made with the twelve (12) month eligibility period, the most recent status shall apply and shall be submitted

to FDA. When a certified interstate shellfish shipper changes status because of certificate revocation, the shipping state shall immediately notify the FDA headquarters office, all known receiving states, the ISSC, and the appropriate FDA Regional Office. Receiving states shall immediately notify shipping states in writing with a copy of irregularities in shellfish received, which may raise questions concerning the source or quality of the product.

- Section 4.** The state shellfish control authorities shall accept responsibility for having trained personnel to implement the state programs. Methods should be developed so that personnel who have completed the training can demonstrate proficiency at appropriate intervals.
- Section 5.** Shellfish growing area patrol activities shall be carried out by an enforcement authority designated by the state in any productive shellfish growing areas failing to meet the approved area criteria of the NSSP.
- Section 6.** All phases associated with the relaying of shellfish from closed areas to approved areas shall be under the immediate supervision of the appropriate responsible state shellfish control authority.
- Section 7.** Depuration may be permitted only under the effective supervision of the state shellfish control authority (ies).
- Section 8.** Laboratories shall be provided and staffed to effectively support the state shellfish program. Sample analysis shall be performed in accordance with the latest approved edition of the APHA, AOAC, or ISSC approved methods.

PROCEDURE IV. RESPONSIBILITIES OF THE FDA

- Section 1.** The FDA should promote uniformity among FDA personnel through a national shellfish-training program, which will be conducted at least every three (3) years. Methods should be developed so that personnel who have completed the course can demonstrate proficiency in lieu of attending the course at subsequent intervals. The FDA should administer an ISSC approved training course at least every three (3) years for state shellfish control personnel. The FDA should evaluate and ensure the uniformity of methods of state shellfish laboratory personnel who are responsible for the operation of the state laboratories. The FDA annual state program evaluation should include: a listing and the date of most recent training of the state shellfish control personnel who have completed the appropriate training, a list of FDA personnel who have completed the appropriate training, and a list of state shellfish laboratory personnel whose competence in interpreting and evaluating shellfish laboratory methods has been demonstrated to and evaluated by the FDA.
- Section 2.** The FDA should publish the ICSSL monthly. The ICSSL should include certification of shellfish shippers as submitted by the states.

Section 3. The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the Regional Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA headquarters.

Section 4. Interpretations of the FDA recommended National Shellfish Sanitation Program and FDA evaluation procedures should be furnished periodically to the state shellfish control authorities. Administrative procedures developed by the FDA should be drafted and forwarded to the ISSC for review and comment prior to their adoption. The ISSC should stand ready to deal with such problems on a continuing basis.

PROCEDURE V. GUIDELINES

The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.

PROCEDURE VI. GROWING WATERS CLASSIFICATION

The state shellfish classification authority shall survey and classify the shellfish growing waters of the state in accordance with the methods outlined in the NSSP. Classification of shellfish growing waters shall be made by qualified state shellfish classification personnel who have successfully completed training. Classification shall be reappraised at least every twelve (12) months, a complete resurvey shall be completed at least every three (3) years, and a comprehensive sanitary survey at least every twelve (12) years.

PROCEDURE VII. SHIPPER CERTIFICATION

A shipper desiring classification of his plant for the purpose of interstate shipment of shellfish shall submit a request to the state shellfish sanitation control authority in his own state. Shellfish sanitation certification inspections shall be made by qualified state shellfish sanitation control personnel who have completed the appropriate training. State shellfish sanitation certification inspections shall be made at least annually. The names, certification numbers, and locations of all certified interstate shippers shall be published monthly in the ICSSL.

PROCEDURE VIII. BILL OF LADING AND LABELING

- Section 1.** All interstate shipments of shellfish must be accompanied by copies of a bill of lading which includes the following information: (a) shipper's name, address and certification number; (b) point of origin of shipment; (c) quantity of product; (d) type of product; (e) date of shipment. All entries on bills of lading shall be legible. When the interstate shipment is derived from more than one shipper, separate bills of lading for each of the sources shall accompany the shipment.
- Section 2.** All individual containers of shellfish in interstate shipment shall be labeled in accordance with applicable FDA and NSSP requirements.

PROCEDURE IX. PROCEDURES FOR HANDLING COMPLAINTS AND CHALLENGES REGARDING THE ADEQUACY OF CERTIFICATION CONTROLS

- Section 1.** Complaints from any state or non-state party regarding possible non-conformities in a producing and/or shipping state shall be handled as follows:
- Subdivision a. Only complaints regarding the sanitary quality and effectiveness of public health controls shall be covered under this procedure.
- Subdivision b. Complaints shall be made in writing to the state shellfish control authority as listed in the ICSSL, with a copy to the appropriate FDA Regional Office.
- Subdivision c. The complaint shall provide specific and complete factual information concerning all items not in conformity and shall specifically verify that all sampling and testing has been conducted in accordance with the NSSP.
- Subdivision d. The state shellfish control authority shall make an investigation of the complaint within twenty (20) working days of receipt, promptly notify the complainant in writing of the findings and any actions being taken, and provide a copy to the appropriate FDA Regional Office.
- Subdivision e. Upon receipt of the response or upon the failure to receive a response within thirty (30) days, the complainant may request in writing to the ISSC Board Chairperson that further investigation by FDA be conducted. FDA may also undertake further investigation at their own initiative.
- Subdivision f. FDA shall provide a written report of its findings or the status of the complainant within thirty (30) days to the parties involved and the ISSC Board Chairperson.
- Subdivision g. If FDA's investigation does not lead to a satisfactory resolution of the problem, the problem shall be handled as an unresolved issue according to Procedure IX. Section 3.
- Section 2.** When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:

Subdivision a. FDA shall provide written notification to the state shellfish control authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.

Subdivision b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.

Subdivision c. When a state does not disagree with FDA findings, but does disagree with an FDA report, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days.

Subdivision d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.

Subdivision e. If FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), or if the state disagrees with FDA's findings or response, it shall be considered an unresolved issue. FDA or the state shall notify the ISSC Executive Director who shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.

Section 3. After receipt of an unresolved issue, the Executive Director shall immediately send the unresolved issue to the Executive Board. Within thirty (30) days of receipt of the unresolved issue by the Executive Director, the Executive Board shall take one (1) of the following actions:

Subdivision a. Resolve the issue on their own initiative.

Subdivision b. Refer the matter to the Unresolved Issues Committee.

Section 4. When an issue has been referred, the Unresolved Issues Committee shall convene a meeting, giving all involved parties an opportunity to participate. The Committee shall review the issue, and considering input from involved parties, submit its recommendations to the Executive Board.

Section 5. The following list of deficiencies and sanctions shall serve as a guide for actions should the Executive Board confirm the findings of the FDA evaluation.

Subdivision a. State program deficiencies, which may result in ISSC sanctions, are as follows:

Subdivision i. Administrative - Inadequate State Laws/Regulations to Enforce the Program

Subdivision ii. Growing Areas

Subdivision (a) Failure to properly classify.

Subdivision (b) Failure to close in an emergency situation.

Subdivision (c) Repeated failure to comply with conditional management plans.

Subdivision (d) Lack of sanitary survey and supporting documentation justifying classifications.

Subdivision (e) Lack of biotoxin contingency plan.

Subdivision (f) Failure to comply with contingency plans.

Subdivision iii. Plant Sanitation

Subdivision (a) Failure to have a standardization officer.

Subdivision (b) Certification of plants by non-standardized inspector.

Subdivision (c) Failure to take action on critical deficiencies.

Subdivision (d) Significant differences between state vs. state/FDA inspections.

Subdivision (e) Repeated Critical and Key items at significant number of firms.

Subdivision (f) Inadequate state laws/regulations to enforce program.

Subdivision iv. Other Program Areas

Subdivision (a) Inadequate tagging and records by shellfish dealers.

Subdivision (b) Refusal to participate/provide cooperation in FDA program evaluations.

Subdivision (c) Failure to control relaying.

Subdivision b. The following actions shall be taken by the Executive Board as appropriate:

Subdivision i. Meeting(s) with responsible state officials to express ISSC concern about the unresolved issue and to develop an acceptable action plan.

Subdivision ii. A letter to top state program administrators, including the governor, expressing ISSC concern regarding state program deficiencies.

Subdivision iii.Notification to ISSC members of the unresolved issue for their information.

Subdivision iv.Recommendation to FDA to include a notice in the ICSSL regarding the unresolved issue.

Subdivision v. Recommendation to the state shellfish control authority to remove affected dealers from the ICSSL.

Subdivision vi.Recommendation to FDA to remove all certified dealers from future ICSSL publications.

Subdivision vii.Notification to all states and other appropriate authorities describing the unresolved issue and that action against products from a state with significant control problems may be appropriate for their consideration.

Subdivision viii.A letter to FDA expressing ISSC concern regarding the position of FDA.

PROCEDURE X. PROCEDURE FOR HANDLING ISSC SUMMARY OF ACTIONS

Unless explicitly specified otherwise by a vote of the voting delegates, recommended changes in the NSSP or Procedures shall be implemented in accordance with the following schedule:

- Section 1.** The Summary of Actions for the Biennial meeting shall be forwarded to FDA within sixty (60) days of the close of the Biennial meeting.
- Section 2.** FDA will review the actions of the ISSC and within sixty (60) days of the receipt will notify the Board Chairperson of the ISSC of which actions conflict with existing federal laws, regulations or policies. NSSP changes, with which FDA concurs, will be effective upon posting on the FDA website unless otherwise stated in the Summary of Actions or in the NSSP Model Ordinance. The Task Force may recommend a specific implementation date.
- Section 3.** For those actions which FDA feels conflict with existing federal laws, regulations or written policies or when a federal law, regulation or written policy does not address the issue, a written decision made by the Director, FDA Office of Seafood, along with supporting rationale, will be provided to the ISSC Chairperson within sixty (60) days of receipt of the Summary of Actions.
- Section 4.** The ISSC Chairperson will refer those actions which FDA feels conflict with existing federal laws, regulations, or written policies with FDA's rationale, to the Executive Board for further discussion or referral to the next Biennial meeting for reconsideration.

PROCEDURE XI. PROCEDURE FOR HANDLING RESOLUTIONS

- Section 1.** The Board Chairperson, with approval of the Board, shall appoint a four-member Resolutions Committee. Membership shall consist of one member from regulatory,

one member from industry, one representative from FDA, and one member from NMFS. The appointment of the Committee and the duties of the Committee will be as outlined in the ISSC Constitution, By-Laws, and Procedures.

Section 2. The objective of the Resolutions Committee shall be to review all proposed resolutions with respect to criteria for content and format and for adherence to time frames for submission and posting to permit adequate review by all Conference participants prior to the final Voting General Assembly. Depending on circumstances and timing, resolutions may be submitted by any Conference member for consideration by the General Assembly or by the Board at interim meetings.

Section 3. For the purpose of resolution procedures, there shall be two types of resolutions.

Subdivision a. Housekeeping resolutions are routine resolutions for acknowledging accomplishments or recognition of services, such as hotel staff and volunteers, for activities performed. Housekeeping resolutions may be submitted at any time prior to the voting of the General Assembly.

Subdivision b. Substantive resolutions are relevant to the objectives to the ISSC. Substantive resolutions shall be submitted to the Resolutions Committee Chairperson no later than two days prior to the issuance of the final Task Force Reports. Copies of the resolutions, including Resolution Committee recommendations, shall be included with the Task Force Reports when they are distributed for membership consideration.

Section 4. There are two prescribed criteria for resolutions.

Subdivision a. Resolutions shall not propose changes in major ISSC policies, the Constitution, By-Laws, or Procedures or the NSSP. These changes are considered Proposals and must be submitted as outlined in Article XIII. of the Constitution for consideration by Task Forces.

Subdivision b. Resolutions shall be submitted uniformly using a standard ISSC Resolution Form.

Section 5. The Resolutions Committee, in reviewing the submitted resolution, may:

Subdivision a. Make editorial changes (grammatical, spelling, or format only); and

Subdivision b. Make substantive changes (must discuss with submitter).

Section 6. The Resolutions Committee shall make recommendations that may include:

Subdivision a. Referral to the General Assembly and/or the Board for consideration; and

Subdivision b. Referral to the Board for assignment to a Task Force for appropriate action.

The Committee must provide in writing its reason for the action it has taken.

**PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING
INTERPRETATIONS OF THE MANUAL BY FDA.**

Section 1. A request for Interpretation must be submitted to FDA Headquarters (Office of Field Programs) through either an FDA Regional Office or the ISSC Executive Director according to the following routes:

Subdivision a. The interpretation request is submitted to the Office of Field Programs following the administrative chain of communication from industry to the State, to the FDA Regional Office, to FDA Headquarters; or

Subdivision b. The interpretation request is submitted to the ISSC Executive Director by industry, a State, or the general public. The ISSC forwards the interpretation request to Office of Field Programs for a response.

Section 2. The interpretation request submitted to Office of Field Programs must be written and include the following:

Subdivision a. The question to be interpreted. Clearly state what the issue(s) is and include the NSSP Guide for the Control of Molluscan Shellfish reference(s) that is unclear and requires interpretation. Include any NSSP Guide for the Control of Molluscan Shellfish references related to the question.

Subdivision b. Who is requesting the interpretation? Give the name, state, area of interest (i.e., an industry person who operates an oyster shucker/packer operation, a State Shellfish Standardization Officer, etc.) and his/her address and phone number.

Subdivision c. The background surrounding the interpretation request. It is very important to understand the circumstances, motivation, and purpose for an interpretation to put it into context.

Subdivision d. An opinion on resolving the problem. Include ideas on what the Interpretation should be. This includes what the NSSP Guide for the Control of Molluscan Shellfish means, the intent of the NSSP Guide for the Control of Molluscan Shellfish, how appropriate reference (CFR, EPA Guidance Document, etc.) should be interpreted.

Section 3. Within seven (7) days, the Office of Field Programs will acknowledge receipt of the letter to the requestor and FDA's Division of Federal and State Relations (DFSR) and report which branch in FDA is responsible for developing the interpretation.

Section 4. All requests for interpretations must be sent to the Office of Field Programs. The Office of Field Programs will decide if the request is a technical or policy issue. The Office of Field Programs will develop technical interpretations and the FDA Office of Seafood will develop policy interpretations. Therefore, in the following subdivisions, if the request is a policy issue, substitute FDA Office of Seafood for Office of Field Programs.

Subdivision a. Within sixty (60) days of acknowledgment of the letter, the Office of Field Programs will provide a draft proposal to the FDA Regional Offices, the ISSC Executive Director, and DFSR for comment. The

ISSC Executive Director shall distribute the draft proposal to the requestor and ISSC members from states, industry, and the general public.

Subdivision b. An additional thirty (30) days may be permitted for draft development if circumstances warrant. The requestor must be notified of the additional development time.

Section 5. Comments on the Draft Interpretation.

Subdivision a. The FDA Office of Seafood, the Regional Offices, ISSC Executive Director, and DFSA have thirty (30) days from receipt to comment on the draft proposal to the Office of Field Programs. The ISSC Executive Director is responsible for receiving, consolidating, and forwarding to the Office of Field Programs comments from ISSC members from states, industry, and the general public.

Subdivision b. The FDA Office of Seafood, the FDA Regional Offices, ISSC Executive Director, and DFSR may request, in writing to the Office of Field Programs, an additional thirty (30) days to comment on the draft proposal.

Section 6. Action on Draft Interpretation Comments.

Subdivision a. The Office of Field Programs has thirty (30) days from receipt of comments to complete the final interpretation by:

Subdivision i. Incorporating the comments and issuing a final interpretation; or

Subdivision ii. Issuing the final interpretation without revision.

Subdivision b. FDA may request an additional thirty (30) days for issuance of the final interpretation if circumstances warrant. The requestor and ISSC Executive Director must be notified of the additional development time.

Section 7. The Office of Field Programs shall disseminate final interpretations to the ISSC and DFSR for dissemination as follows:

Subdivision a. Upon receipt of the final interpretation, the ISSC Executive Director shall distribute it to the requestor and ISSC members from states, industry, and the general public.

Subdivision b. Upon receipt of the final interpretation, DFSR shall distribute it to the FDA Regional Offices and the Office of Field Programs.

PROCEDURE XIII. PROCEDURE FOR INCORPORATION OF APPENDICES INTO THE NSSP MODEL ORDINANCE.

Reference materials related to Satisfactory Compliance will be included in the NSSP Model Ordinance. All other reference materials will be referenced by title only.

**PROCEDURE XIV. PROCEDURE FOR ADDRESSING PATHOGENS AND
DELETERIOUS SUBSTANCES NEWLY RECOGNIZED IN
SHELLFISH.**

Section 1. Issues or concerns regarding pathogen(s) or deleterious substances newly recognized in shellfish, which may not be presently addressed in the NSSP submitted to the Conference for action, shall be immediately referred to the Pathogen Review Committee. The committee shall review the issue or concern, gather information, and provide a written report and recommendation to the Executive Board or Task Force for appropriate action. The intent of this procedure is to provide a base of knowledge in an expeditious manner for effective action by the ISSC. The written report shall include:

Subdivision a. Characterization of the pathogen or deleterious substance. Characterization shall address, as a minimum, the following:

Subdivision i. The illness and symptoms

Subdivision ii. Dose/response relationship

Subdivision iii. Route of transmission

Subdivision iv. Incidence of illness

Subdivision v. Population affected

Subdivision vi. Source of pathogen

Subdivision vii. Pollution level association

Subdivision viii. Geographic scope

Subdivision ix. Type of shellfish implicated

Subdivision b. A detailed summary of the literature search conducted by the committee. The search shall include, as a minimum, the following:

Subdivision i. Published literature

Subdivision ii. Grey literature

Subdivision iii. White papers

Subdivision iv. Personal communication

Subdivision c. Recommendation on the adequacy of present NSSP or other controls in addressing the pathogen or deleterious substance.

Subdivision d. Recommendation of additional NSSP controls or alternative controls if appropriate.

Subdivision e. Recommendation of additional data or information needs critical to development of effective controls.

Section 2. The Pathogen Review Committee shall include representatives from FDA, NMFS, EPA, State shellfish control authorities, the shellfish industry, and academia with knowledge of the pathogen(s) or deleterious substances of concern and risk analysis and risk management.

Section 3. The ISSC Executive Board shall set a date for completion of the report to ensure that the ISSC membership is informed. The written committee report shall be presented to the Executive Board or appropriate Task Force for use in its deliberation of the issue.

**PROCEDURE XV. PROCEDURE FOR EVALUATION OF SHELLFISH SANITATION
PROGRAM ELEMENTS.**

- Section 1.** The goal of shellfish program evaluation shall be to monitor program implementation and work with states to determine where problems may exist and how to address them.
- Section 2.** Shellfish program evaluation methodologies shall:
Subdivision a. Monitor state program implementation;
Subdivision b. Assess state program effectiveness; and
Subdivision c. Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish.
- Section 3.** The minimum components of shellfish program evaluation shall include:
Subdivision a. A description of the program activity;
Subdivision b. A comparison of FDA observations with state observations; and
Subdivision c. A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.
- Section 4.** The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.
- Section 5.** The types of data collected shall include the following:
Subdivision a. Program records;
Subdivision b. Direct observation made by the evaluator;
Subdivision c. Data and information from the Authority or other pertinent sources.
- Section 6.** Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum:
Subdivision a. Evaluation of growing area classification;
Subdivision i. Records audit of sanitary survey;
Subdivision ii. Bacteriological standards;
Subdivision iii. Growing area classification;
Subdivision iv. Marine biotoxin control;
Subdivision v. Marinas.
Subdivision b. Evaluation of shellfish plant inspection program;
Subdivision i. Records audit of past shellfish processing facility inspections;
Subdivision ii. Direct observation of current shellfish processing facility conditions;
Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.
Subdivision iv. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the

same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:

- (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.
- (b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.
- (c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.
- (d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the state.
- (e) All critical deficiencies have been addressed by the state inspector in accordance with the Guide for the Control of Molluscan Shellfish.

- Subdivision c. Evaluation of shellfish laboratories;
 - Subdivision i. Records audit of laboratory operations;
 - Subdivision ii. Direct observation of current laboratory operating conditions;
 - Subdivision iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.
- Subdivision d. Evaluation of shellfish growing area patrol;
 - Subdivision i. Records audit of past patrol activities;
 - Subdivision ii. Direct observation of current patrol activities;
 - Subdivision iii. Information collection from the Authority and other pertinent sources.

PROCEDURE XVI. PROCEDURE FOR THE APPROVAL OF ANALYTICAL METHODS FOR THE NSSP.

- Section 1.** Systematic evaluation of the analytical method using the validation criteria developed by the ISSC as detailed in the Single Laboratory Validation Protocol;
- Section 2.** Proposal to the ISSC requesting approval of the analytical method for use in the NSSP;
 - Subdivision a. Submission of the Proposal;

Subdivision b. Proposal presented to Executive Director for Committee review and consideration for acceptance.

Section 3. Review by Laboratory Methods Review Committee;

Subdivision a. Committee review and evaluation of the data submitted describing the performance characteristics of the method;

Subdivision i. These performance characteristics include:

Subdivision (a) Accuracy (Trueness);

Subdivision (b) Measurement uncertainty;

Subdivision (c) Precision

Subdivision (d) Recovery;

Subdivision (e) Specificity;

Subdivision (f) Linear range;

Subdivision (g) Limit of detection;

Subdivision (h) Limit of quantitation
(sensitivity);

Subdivision (i) Ruggedness;

Subdivision (j) Comparability if applicable
(comparison of the
performance of the
new/modified method to the
accepted method.

Subdivision ii. Method documentation including:

Subdivision (a) Method title, scope and
references;

Subdivision (b) Equipment and reagents
required;

Subdivision (c) Sample collection, preservation
and storage requirements;

Subdivision (d) Safety requirements;

Subdivision (e) Step by step procedure;

Subdivision (f) Specific quality control
measures associated with the
method;

Subdivision (g) Cost of the method;

Subdivision (h) Sample turnaround time.

Subdivision iii. Specific application(s);

Subdivision b. Review of need for the method;

Subdivision i. Method meets an immediate or continuing need;

Subdivision ii. Improves analytical capability under the NSSP as
an alternative to an accepted method(s);

Subdivision iii. Replaces other approved or accepted method(s).

Section 4. Possible Actions by the Laboratory Methods Review Committee;

Subdivision a. Non-acceptance pending further information as defined by the
Committee;

- Subdivision b. Accept as a Type IV Method;
- Subdivision c. Accept as a Type III Method;
- Subdivision d. Accept as a Type III Method, and recommend adoption as Type II or Type I Method;
- Subdivision e. Rescind acceptance for cause (the need no longer exists, poor performance, equipment or reagents no longer available, etc.)

- Section 5.** Task Force recommendation (or non-recommendation) for adoption by ISSC;
- Section 6.** Adoption (or non-adoption) by ISSC General Assembly;
- Section 7.** Review and Acceptance by FDA Office of Food Safety in the Summary of Actions;
- Section 8.** Addition to/removal from the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods.

Section 9. Types of NSSP analytical methods.

- Subdivision a. Type I Methods. Type I methods are methods accepted for use in the NSSP and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:
 - Subdivision i. Described in a scientific or other peer-reviewed professional publication;
 - Subdivision ii. Used successfully to detect or quantify;
 - Subdivision iii. Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;
 - Subdivision iv. Collaboratively studied and/or collaboratively tested; and/or,
 - Subdivision v. Long used as an accepted method in the NSSP. Examples: APHA MPNs for total and fecal coliforms, Modified A-1 MPN (MA-1), and the mouse bioassay for saxitoxins (PSP).
- Subdivision b. Type II Methods. Type II methods are methods accepted for use in the NSSP and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:
 - Subdivision i. Described in a scientific or other peer-reviewed professional publication;
 - Subdivision ii. Used successfully to detect or quantify;

- Subdivision iii. Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;
 - Subdivision iv. Long used and accepted for use in the NSSP. Examples: Elevated temperature coliform pour plate method (ETCP) and the mouse bioassay for brevetoxins (NSP).
- Subdivision c. Type III Methods. Type III methods include those methods accepted by unanimous vote of the Laboratory Methods Review Committee for use on an interim basis and cited in the *NSSP Guide for the Control of Molluscan Shellfish*, Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:
- Subdivision i. Described in a scientific or other peer-reviewed professional publication;
 - Subdivision ii. Used successfully to detect or quantify;
 - Subdivision iii. Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;
 - Subdivision iv. Selected to fulfill a continuing need;
 - Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation or deletion.
- Subdivision d. Type IV Methods. Type IV methods include those methods accepted by majority vote of the Laboratory Methods Review Committee for use on an interim basis and cited in the *NSSP Guide for the Control of Molluscan Shellfish*, Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotxin Analytical Methods that have been:
- Subdivision i. Described in a scientific or other peer-reviewed professional publication;
 - Subdivision ii. Used successfully to detect or quantify;
 - Subdivision iii. Evaluated, and the performance characteristics for specific applications have been determined and found fit for purpose;
 - Subdivision iv. Selected to fulfill an immediate need;
 - Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation or deletion.

PROCEDURE XVII. RECIPROCITY

Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in

excess of the requirements of the NSSP or the ISSC agreements. The intent of this procedure is to ensure that state actions do not unnecessarily restrict interstate shipment of shellfish conforming to the reciprocity of the NSSP. The ISSC recognizes that states should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. Chapter XVII. Section 1. Notification and Consultation provides adequate opportunity for communication between interested parties that could include state and federal regulatory agencies and the industry.

Section 1. Notification and Consultation

A state, prior to taking an action that may fail to meet the definition of “reciprocity,” must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take the action. The state should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that state;
- The potential effect on the public health in other states;
- The potential economic impact on states;
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I requirements relating to uniformity and the importance of operating within a collective framework.

A state may also notify the ISSC Executive Board upon learning of another state’s intention to take action that may violate Procedure V.

Section 2. Consideration

If, after fully considering the state’s rationale for the proposed actions, the Executive Board determines that the state’s actions are unwarranted and contrary to the interests of the collective membership, the Executive Board shall so advise the state. If the State takes the proposed action after being so advised, or fails to follow Procedure V, the Executive Board will commence a formal Procedure V process.

Section 3. Formal Procedure V. Process

The process will include written notification to all states involved (initiating and affected states), to present findings on the scientific and public health issues raised, which support their respective views or actions on the issue, along with identification of the formal procedural process and timeline.

All affected states (initiating and affected states), shall present the following information to the ISSC Executive Board:

- Scientific and related public health issues;
- Economic issues;
- Other relevant issues;
- Rationale why Procedure V has/has not been violated.
- Alternate Actions for consideration.

The Executive Board determination will include Findings of Facts and Conclusions.

Section 4. Censure

If the state takes the proposed action after being so advised, or fails to follow Procedure V, the Executive Board may place the state under censure until such time as removed from the censure by the Executive Board and so inform the governor of that state in writing. A state under censure may attend all functions and otherwise exercise rights as a member of the ISSC, but may not vote, either in committees, task forces, or in the general assembly. The Executive Board reserves the right to take additional actions against the non-compliant State.