The Interstate Shellfish Sanitation Conference deliberated the issues presented to Task Force II and took the following actions. Note: Bold and underline denotes text to be added; ~~strikeout denotes text to be deleted~~.

SUE NUMBER: 97-205

SPECIFIC REFERENCE: 1999 Model Ordinance Definition (92)(a).

TEXT OF ISSUE:

REQUESTED ACTION #1: Modify 1999 Model Ordinance Definition (92)(a), by adding new subsection (iii):

(iii) Raw, where processing is insufficient to ensure the destruction of vegetative cells of microorganisms of public health concern; and

Renumber existing subsection iii. to iv.

REQUESTED ACTION #2: Propose that the ISSC explore the utility of modifying the Model Ordinance to set forth nomenclature and handling procedures for molluscan shellfish which falls under the "raw" category (as described above) for shellfish, e.g. mildly heat treated shellfish. Particular attention should be given to processing controls and traceability requirements to ensure the integrity of the Model Ordinance and dealer certification process.

PUBLIC HEALTH SIGNIFICANCE:
1. The present Model Ordinance definition does not include raw processed products. Such products may have received mild heat treatment so they cannot be labeled fresh, but the treatment was insufficient to kill a broad spectrum of microorganisms, making Model Ordinance controls necessary to protect public health. The proposed wording is consistent with the HACCP regulation, Subpart C - raw molluscan shellfish.

2. The collective integrity of Model Ordinance safeguards requires proper product identification, handling, traceability, and dealer certification. Developing a rationale and consensus for applying these controls to new products will help provide industry with needed guidance in developing new products to meet emerging public health concerns and consumer demands.

COST INFORMATION: N/A

ACTION BY 1997 TASK FORCE II: Recommended referral of Issue 97-205 to appropriate committee as determined by the Conference Chairman.

ACTION BY 1997 GENERAL ASSEMBLY: Adopted recommendation of 1997 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 1998 PROCESSING/HANDLING COMMITTEE:

FINDINGS: The committee discussed the need for definitions of shellstock, live vs. dead, raw, frozen and other product forms. This discussion occurred in consideration of this issue as well as in reference to the Product Enhancement Subcommittee's report with regard to Issue 98-219. There are broad opinions as to how the Conference should address products in other than the traditional "shucked" or "shellstock" forms.

CONCLUSIONS: In light of these new product forms appearing before the Conference, the ISSC should consider developing definitions for "processing" and "handling", "raw", and other processed product forms.

RECOMMENDATIONS: Refer Issue 97-205 to committee.

ACTION BY 1998 TASK FORCE II: Recommended referral to appropriate committee as determined by the Conference Chairman.

ACTION BY 1998 GENERAL ASSEMBLY: Adopted recommendation of 1998 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 1999 PROCESSING AND HANDLING COMMITTEE:

FINDINGS: There is room for further work on definitions of several terms commonly used in the Model Ordinance. Some of these terms arise as a result of developments in new product forms and new processes that are being used.

CONCLUSIONS: A new chapter encompassing the different types of post harvest processing may be appropriate, but is beyond the charge given to the committee. In addition, the committee felt that the scope of any new Model Ordinance section should be determined and any such section designed prior to developing these new definitions. To do otherwise may limit the work of those writing such a new section and would lead to conflicts with existing provisions of the Model Ordinance.

RECOMMENDATIONS: The committee recommended that the Task Force refer Issue 97-205 to the committee appointed as a result of the Definitions Committee's action on issue 98-219 and that the charge to the committee should be broadened to include post harvest processing with the recommendation that the committee ensure consistency with other Model Ordinance sections.

ACTION BY 1999 TASK FORCE II: Recommended adoption of 1999 Processing and Handling Committee recommendations on Issue 97-205.

ACTION BY 1999 GENERAL ASSEMBLY: Adopted recommendation of 1999 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2000 VIBRIO MANAGEMENT COMMITTEE: Recommended Task Force II refer Issue 97-205 to appropriate committee for development of a new Post Harvest Treatment (PHT) section.

ACTION BY 2000 TASK FORCE II: Recommended adoption of 2000Vibrio Management Committee recommendation.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2001 COMMITTEE: No Committee Action**.**

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 97-205 to appropriate Committee as determined by Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

* * *

ISSUE NUMBER: 99-202

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII.03 OPTION 1, OPTION 2, and OPTION 3

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03 OPTION 1, by adding new paragraph F.:

F. The Authority shall require that each harvester maintain a record of the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §A.

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03 OPTION 2, by adding new paragraph D.:

D. The Authority shall require that each harvester maintain a record of the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §B.(1) and §B.(2).

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03 OPTION 3, by adding new paragraph E.:

E. The Authority shall require that each harvester maintain a record of the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §D.

PUBLIC HEALTH SIGNIFICANCE: The NSSP Model Ordinance sets forth time to temperature requirements following harvest of shellstock. However, there is no requirement for harvesters to maintain a record/log of the time of harvesting of each container or lot of shellstock began. Without this information, it is difficult, if not impossible, for dealers to determine whether or not product received from a harvester is within appropriate time to temperature requirements as set forth in Chapter VIII.03.

COST INFORMATION: Adoption of this issue should result in no appreciable cost to industry or regulatory authorities.

ACTION BY 1999 TASK FORCE II: Recommended No Action. Rationale: Issue 99-202 is adequately addressed in the Model Ordinance.

ACTION BY 1999 GENERAL ASSEMBLY: Rejected recommendation of 1999 Task Force II. The General Assembly referred Issue 99-202 to appropriate committee as determined by the Conference Chairman.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2000 RECORD KEEPING SUBCOMMMITTEE: The Record Keeping Subcommittee recommended the following language changes to Issue 99-202:

Modify Model Ordinance Chapter VIII.03 OPTION 1, PAGE ~~54~~ **62** by adding new paragraph F.:

F. The Authority shall require that each harvester ~~maintain a~~ record**, via tag, log etc.,** ~~of~~ the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §A.

Modify Model Ordinance Chapter VIII.03 OPTION 2, PAGE ~~54~~ **63** by adding new paragraph D.:

D. The Authority shall require that each harvester ~~maintain a~~ record**, via tag, log etc.,** ~~of~~ the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in ~~§B.(1) and §B.(2)~~ **§C**.

Modify Model Ordinance Chapter VIII.03 OPTION 3, PAGE ~~55~~ **64** by adding new paragraph D.:

D. The Authority shall require that each harvester ~~maintain a~~ record**, via tag, log etc.,** ~~of~~ the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §C.

ACTION BY 2000 PROCESSING AND HANDLING COMMITTEE: The Processing and Handling Committee concluded that this matter is already being addressed through requirements at the state level in the most affected states. If adopted, the new requirement would impose a burden on other states with significant regional harvesting differences. It was apparent from the Processing and Handling Committee deliberations that there is considerable confusion related to the Time/Temperature Matrices and the products to which they apply. The Processing and Handling Committee did not concur with the Subcommittee's recommendations. The Processing and Handling Committee recommended No Action on Issue 99-202.

ACTION BY 2000 TASK FORCE II: Recommended adoption of Processing and Handling Committee recommendation of No Action. Rationale: The Processing and Handling Committee concluded that this matter is already being addressed through requirements at the state level in the most affected states. If adopted, the new replacement would impose a burden on other states with significant regional harvesting differences.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY USFDA: Does not concur with action taken by Conference. Recommended Issue 99-202 be returned to an appropriate committee for further consideration.

ACTION BY ISSC EXECUTIVE BOARD: Referred Issue 99-202 to an appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 TIME TEMPERATURE COMMITTEE: Recommended adoption of the following replacement language for the three requested actions proposed in the issue**:**

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03 OPTION 1, by adding new paragraph F.:

~~**F. The Authority shall require that each harvester maintain a record of the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §A**~~

F. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03 OPTION 2, by adding new paragraph D.:

~~**D. The Authority shall require that each harvester maintain a record of the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §B.(1) and §B.(2).**~~

D. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03 OPTION 3, by adding new paragraph E.:

~~**E. The Authority shall require that each harvester maintain a record of the time harvesting began for each container or lot of shellfish harvested. Records shall be used by shellfish dealers to assure that shellstock is refrigerated within the time periods specified in §D.**~~

E. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

ACTION BY 2001 TASK FORCE II: Recommended adoption of 99-202 as recommended by the Time Temperature Committee.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

* * *

ISSUE NUMBER: 99-209

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter XI.01B. and D.; 1997 Chapter XI.03H.; 1999 Chapter XII.01A., B. and C; 1997 Chapter XII.03.H.; 1999 Chapter XIII.01B.; 1999 Chapter XIII.03H.; 1999 Chapter XIV.01A., B. and C.; 1999 Chapter XIV.03H.

TEXT OF ISSUE:

REQUESTED ACTION #1: Modify 1999 Model Ordinance Chapter XI.01B. and D.:

B. Shellstock Storage Critical Control Point - Critical Limit. The dealer shall ensure **that:**

(1) If wet storage ...; and

(2) Once placed under temperature control ~~and until sale to the processor or final consumer,~~ shellstock shall be~~;~~ **cooled to an internal temperature of:**

~~(a) Iced; or~~

~~(b) Placed and stored in a storage area or conveyance maintained at 45? Fahrenheit (7.2? Centigrade) or less; and.~~

~~(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B(1) or B(2) for more than 2 hours at points of transfer such as loading docks.~~

(a) 70? Fahrenheit (21? Centigrade) within 2 hours; and

(b) 50? Fahrenheit (10? Centigrade) within 4 hours; and

(3) Once chilled to 50? Fahrenheit (10? Centigrade), shellstock shall not exceed an internal temperature of 50? Fahrenheit (10? Centigrade) for more than 1 hour.

C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been ... three hours of shucking.

(2) For shellstock refrigerated prior ... removal from refrigeration.

(3) If heat shock is used ... heat shock process.

D. Shucked Meat Storage Critical Control Point - Critical Limit. ~~The dealer shall store shucked and packed shellfish in covered containers at an ambient air temperature in the storage area of 45? Fahrenheit (7.2? Centigrade) or less.~~ **Shucked and packed shellfish shall not exceed an internal temperature of 45? Fahrenheit (7.2o Centigrade) for more than 1 hour.**

REQUESTED ACTION #2: Modify 1997 Model Ordinance Chapter XI.03H., by adding new subsection (4): *[Ed. note: This reference does not appear in the 1999 revision.]*

(4) The dealer shall ensure that:

(a) Shellstock is placed and stored in a storage area or conveyance maintained at 45? Fahrenheit (7.2? Centigrade) or less;

(b) Shucked and packed shellfish is stored in covered containers at an ambient air temperature in the storage area of 45? Fahrenheit (7.2? Centigrade) or less;

(c) If containers having a capacity of one gallon (128 ounces or 3785 milliliters) or more are used, the shucked meats shall be chilled to 45? Fahrenheit (7.2? Centigrade) or less prior to packing.

Renumber subsequent subsections.

REQUESTED ACTION #3: Modify 1999 Model Ordinance Chapter XII.01A., B. and C.:

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:

(1) Originated from a dealer; ~~and~~

(2) Are identified with a label as outlined in Chapter X.06~~.~~ **; and**

(3) Has an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less.

B. Processing Critical Control Point- Critical Limits. The dealer shall ensure that repacked shellfish ~~are~~ **do not exceed an internal temperature of 45? Fahrenheit (7.2? Centigrade) for more than 2 hours.**

~~(1) Maintained at an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less; and~~

~~(2) Maintained at a temperature less than 45? Fahrenheit (7.2? Centigrade) in any portion of frozen shellfish thawed for repacking.~~

C. Shucked Meat Storage Critical Control Point - Critical Limit. ~~The dealer shall store repacked shellfish in covered containers at an ambient air temperature of 45? Fahrenheit (7.2? Centigrade) or less.~~ **Repacked shellfish shall not exceed an internal temperature of 45? Fahrenheit (7.2? Centigrade) for more than 1 hour.**

REQUESTED ACTION #4: Modify 1997 Model Ordinance Chapter XII.03H., by adding new subsection (4): *[Ed. note: This reference does not appear in the 1999 revision.]*

(4) The dealer shall ensure that:

(a) Shucked and packed shellfish is stored in covered containers at an ambient air temperature in the storage area of 45? Fahrenheit (7.2? Centigrade) or less;

(b) If containers having a capacity of one gallon (128 ounces or 3785 milliliters) or more are used, the shucked meats shall be chilled to 45? Fahrenheit (7.2? Centigrade) or less prior to packing.

Renumber subsequent subsections.

REQUESTED ACTION #5: Modify 1999 Model Ordinance Chapter XIII.01B.:

B. Shellstock Storage Critical Control Point - Critical Limit. The dealer shall ensure that:

(1) If wet storage ... outlined in Chapter X.08; ~~and~~

(2) Once placed under temperature control ~~and until sale to the processor or final consumer,~~ shellstock shall be **cooled to an internal temperature of**:

~~(a) Iced; or~~

~~(b) Placed and stored in a storage area or conveyance maintained at 45? Fahrenheit (7.2? Centigrade) or less; and~~

~~(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration for more than 2 hours.~~

(a) 70? Fahrenheit (21? Centigrade) within 2 hours; and

(b) 50? Fahrenheit (10? Centigrade) within 4 hours; and

(3) Once chilled to 50? Fahrenheit (10? Centigrade), shellstock shall not exceed an internal temperature of 50? Fahrenheit (10? Centigrade) for more than 1 hour.

REQUESTED ACTION #6: Modify 1999 Model Ordinance Chapter XIII.03H., by adding new subsection (4):

(4) The dealer shall ensure that shellstock is placed and stored in a storage area or conveyance maintained at 45? Fahrenheit (7.2? Centigrade).

Renumber subsequent subsections.

REQUESTED ACTION #7: Modify 1999 Model Ordinance Chapter XIV.01A., B., and C.:

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:

(1) Originate from a dealer;

(2) Are identified with a tag as outlined in Chapter X.05 or a label as outlined in Chapter X.06~~.~~ **; and**

(3) Has an internal temperature of 50? Fahrenheit (10? Centigrade) or less for shellstock or 45? Fahrenheit (7.2? Centigrade) for shucked shellfish.

B. Shellstock Storage Critical Control Point - Critical Limit. ~~The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:~~

~~(a) Iced; or~~

~~(b) Placed and stored in a storage area or conveyance maintained at 45? Fahrenheit (7.2? Centigrade) or less; and~~

~~(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration for more than 2 hours at points of transfer such as loading docks.~~

The dealer shall ensure than shellstock does not exceed an internal temperature of 50? Fahrenheit (10? Centigrade) for more than 1 hour.

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall ~~store shucked shellfish at a temperature of 45? Fahrenheit (7.2? Centigrade) or less.~~ **ensure that shucked shellfish does not exceed an internal temperature of 45? Fahrenheit (7.2? Centigrade) for more than 1 hour.**

REQUESTED ACTION #8: Modify 1999 Model Ordinance Chapter XIV.03H., by adding new subsection (3):

(3) The dealer shall:

(a) Ice or place and store shellstock in a storage area or conveyance maintained at 45? Fahrenheit

(7.2° Centigrade) or less;

(b) Store shucked shellfish at an ambient air temperature of 45° Fahrenheit (7.2° Centigrade) or less.

Renumber subsequent subsections.

PUBLIC HEALTH SIGNIFICANCE: Existing critical limits for time/temperature control in shellfish processing are generally directed at ambient air temperatures rather than product temperatures, offer little or no allowance for temperature variations associated with product processing, and offer little or no flexibility in the time allowed to exceed final product temperature. As such, existing Model Ordinance critical limits are extremely restrictive and have no scientific basis for public
health protection. The proposed changes outlines in this issue establish critical limits for shellstock and shucked shellfish processing which: (1) are based on scientifically recognized time/temperature requirements prescribed in

FDA's "Fish and Fisheries Products Hazards and Controls Guide", (2) provide allowances for exceeding optimum product holding temperatures while controlling pathogen growth and maintaining product safety, and (3) provide a set of critical limits which can be reasonable implemented by industry and enforced by shellfish control authorities.

Existing critical limits, however, serve as good GMPs and as such should be retained as part of the Model Ordinance under Section .03 of the processing chapters.

COST INFORMATION: N/A

[Ed. Note: At the request of the FDA, the ISSC Executive Board appointed a work group to review the Model Ordinance Critical Limits. To facilitate development of a 1999 issue, a draft issue was created (99-209) and provided to the work group for comments. The schedule for issue submission process did not allow the time necessary to integrate the work group's comments into the draft issue. This issue (99-209) was included in the issue package as originally drafted. The comments of the work group were forwarded to the 1999 Time/Temperature Subcommittee which is addressing a similar issue (98-211). The Subcommittee provided the following comments on Issue 99-209.]

COMMENTS BY 1999 TIME/TEMPERATURE SUBCOMMITTEE: The Subcommittee discussed the practicality and need for this issue given HACCP and the record keeping requirements it might create. In reviewing Issue 99-209, the Time/Temperature Subcommittee was also concerned with the need for so many specific prescriptions on temperature recording and critical limits.

The committee further commended that Issue 99-209 is contrary to the philosophy of HACCP and that certain requirements in the issue may be detrimental to live shellstock quality and survival.

ACTION BY 1999 TASK FORCE II: Recommended referral of Issue 99-209 to appropriate committee as determined by the Conference Chairman.

ACTION BY 1999 GENERAL ASSEMBLY: Adopted recommendation of 1999 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2000 TIME/TEMPERATURE SUBCOMMITTEE:

REQUESTED ACTION #1: Modify 1999 Model Ordinance Chapter XI.01B. and D:

The Subcommittee recommended No Action on Requested Action #1. Rationale: Shellstock and shucked meat temperature controls are adequately addressed in the Model Ordinance and the use of more specific time-temperature critical limits could be managed through the dealer's individual HACCP plans where specific factors such as the type of operation, the species of shellfish and transportation factors are considered. Unrealistic and burdensome tracking, monitoring and record keeping of unrelated lots of shellfish received at various time frames would result if Requested Action #1 were adopted..

REQUESTED ACTION #2: Modify 1997 Model Ordinance Chapter XI.03H. by adding new subsection (4). [*Ed. note: This reference does not appear in the 1999 revision.]*

The Subcommittee recommended No Action on Requested Action #2. Rationale: The provisions are already addressed as a critical control point and critical limit in Chapter XI.01 in the Model Ordinance. Adding Requested Action #2 to ChapterXI.03 of the Model Ordinance would create duplication.

REQUESTED ACTION #3: Modify 1999 Model Ordinance Chapter XII.01A., B., and C:

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:

(1) Originated from a dealer; ~~and~~

(2) Are identified with a label as outlined in Chapter X.06~~.~~ **; and**

(3) Has an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less.

The Subcommittee recommended the following language in paragraph A.(3) as amended:

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:

(1) Originated from a dealer;

(2) Are identified with a label as outlined in Chapter X.06; and

(3) Has an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less **or is adequately packed with ice or other approved methods of refrigeration**.

The Subcommittee recommended adoption of paragraph B. as submitted because the language provides time criteria for repacking shucked shellfish.

The Subcommittee recommended No Action on paragraph C. Rationale: This would require containers to be opened and storage temperature would have to be monitored every hour.

REQUESTED ACTION #4: Modify 1997 Model Ordinance Chapter XII.03H., by adding new subsection (4): [*Ed. note: This reference does not appear in the 1999 revision.]*

The Subcommittee recommended No Action on Requested Action #4 . Rationale: These criteria are already addressed as critical control points and critical limits in Chapter XII.01 of the Model Ordinance.

REQUESTED ACTION #5: Modify 1999 Model Ordinance Chapter XIII.01B.

The Subcommittee recommended No Action on Requested Action #5. Rationale: Shellstock and shucked meat temperature controls are adequately addressed in the Model Ordinance and the use of more specific time-temperature critical limits should be managed through the dealer's individual HACCP plans where specific factors such as the type of operation, the species of shellfish and transportation factors are considered. Unrealistic and burdensome tracking, monitoring and record keeping of unrelated lots of shellfish received at various time frames would result if Requested Action #5 were adopted.

REQUESTED ACTION #6: Modify 1999 Model Ordinance Chapter XIII.03H., by adding new subsection (4):

The Subcommittee recommended No Action on Requested Action #6. Rationale: Temperature controls for shellstock are already addressed as a critical control point and critical limit in Chapter XIII.01. Adding this language to the Chapter XIII.03 section would be a duplication.

REQUESTED ACTION #7: Modify 1999 Model Ordinance Chapter XIV.01A., B., and C:

The Subcommittee recommended that the following language in paragraph A.(3) as amended:

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:

(1) Originate from a dealer;

(2) Are identified with a tag as outlined in Chapter X.05 or a label as outlined in Chapter X.06; and

~~(3) Has an internal temperature of 50? Fahrenheit (10? Centigrade) or less for shellstock or 45? Fahrenheit (7.2? Centigrade) for shucked shellfish.~~

(3) Has an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less **or is adequately packed in ice**

or other approved method of refrigeration.

Recommended final language for paragraph A.(3) shall be:

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
(1) Originate from a dealer;
(2) Are identified with a tag as outlined in Chapter X.05 or a label as outlined in Chapter X.06; and
(3) Has an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less or is adequately packed in ice or other approved method of refrigeration.

The Subcommittee recommended No Action on paragraphs B. and C. and further recommended that an appropriate committee review the feasibility and necessity relating to the monitoring and recording of time and temperature critical limits relating to reshipping.

REQUESTED ACTION #8: Modify 1999 Model Ordinance Chapter XIV.03H., by adding new subsection (3).

The Subcommittee recommended No Action on Requested Action #8. Rationale: The language is already referenced as a critical control point and critical limit in Chapter XIV.01 of the Model Ordinance.

ADDITIONAL RECOMMENDATIONS:

The Subcommittee further recommended that critical control points and critical limits and their impact be considered by an appropriate committee of the Conference. The assigned committee should also consider internal or ambient critical control limits at receiving for shellstock.

ACTION BY 2000 PROCESSING/HANDLING COMMITTEE: The Processing and Handling Committee concurs with the requested actions 1,2,3,4,5,6 and 8 as amended by the Time/Temperature Subcommittee. The recommendations are as follows:

The Processing and Handling Committee did not concur with the Time/Temperature Subcommittee's recommendation on Requested Action #7 and recommended it be amended as follows:

REQUESTED ACTION #7: A. Receiving Critical Control Point-Critical Limits. The dealer shall reship only shellfish which:
(1) Originate from a dealer;
(2) Are identified with a tag as outlined in Chapter X.05 or a label as outlined in Chapter X.06; and
(3) **Shucked shellfish is received in a conveyance with an ambient** ~~Has an internal~~ temperature of 45° Fahrenheit (7.2° Centigrade) or less ~~for shucked shellfish~~ or is adequately packed in ice or other approved method of refrigeration.

The Subcommittee recommended No Action on paragraphs B. and C. ~~and further recommended that an appropriate committee review the feasibility and necessity relating to the monitoring and recording of time and temperature critical limits relating to reshipping.~~

The Processing and Handling Committee recommended No Action on the Time/Temperature Subcommittee's "ADDITIONAL RECOMMENDATIONS".

~~ADDITIONAL RECOMMENDATIONS:~~
~~The sub-committee further recommended that critical control points and critical limits and their impact be considered by an appropriate committee of the conference. The assigned committee should also consider internal or ambient critical control limits at receiving for shellstock.~~

ACTION BY 2000 TASK FORCE II: Recommended adoption of 2000 Processing and Handling Committee recommendations of No Action on Requested Actions # 1, 2, 4, 5, 6 and 8.

Recommended adoption of Requested Action #3 as recommended by 2000 Processing and Handling Committee.

Modify 1999 Model Ordinance Chapter XII.01A.and B.as follows:

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:

(1) Originated from a dealer; ~~and~~

(2) Are identified with a label as outlined in Chapter X.06 **; and**

(3) Has an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less or is adequately packed with ice or other approved methods of refrigeration.

B. Processing Critical Control Point- Critical Limits. The dealer shall ensure that repacked shellfish ~~are~~ **do not exceed an internal temperature of 45? Fahrenheit (7.2? Centigrade) for more than 2 hours.**

~~(1) Maintained at an internal temperature of 45? Fahrenheit (7.2? Centigrade) or less; and~~

~~(2) Maintained at a temperature less than 45? Fahrenheit (7.2? Centigrade) in any portion of frozen shellfish thawed for repacking.~~

Recommended adoption of Requested Action #7 as recommended by 2000 Processing and Handling Committee and further amended as follows:

Modify 1999 Model Ordinance **Chapter XI.01A., Chapter XIII.01A.,** Chapter XIV.01A., B., and C.

A. Receiving Critical Control Point-Critical Limits. The dealer shall reship only shellfish which:

(1) Originate from a dealer;

(2) Are identified with a tag as outlined in Chapter X.05 or a label as outlined in Chapter X.06; and

(3) Shucked shellfish is received in a conveyance with an ambient temperature of 45? Fahrenheit (7.2? Centigrade) or less or is adequately packed in ice or other approved method of refrigeration.

Task Force II further recommended establishment of an appropriate committee as determined by the Conference Chairman to consider the addition of a temperature Critical Control Limit for receiving of shellstock.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY USFDA: Does not concur with action taken by Conference. Recommended Issue 99-209 be returned to an appropriate committee for further consideration.

ACTION BY EXECUTIVE BOARD: Referred Issue 99-209 to appropriate committee as determined by the Conference Chairman.
[Ed. Note: Incorporation of a receiving critical control point-critical limit for shucked shellfish is inappropriate for Chapters XI. And XIII. The requirements in these chapters address activities, which do not include receipt of shucked shellfish. For this reason, the proposed language as recommended in Requested Action #7 will not be incorporated into Chapters XI. And XIII.]

ACTION BY 2001 TIME-TEMPERATURE COMMITTEE: Recommended No Action. Rationale: This issue, as proposed, conflicts with many sections of the manual. The committee further recommended the formation of a working group that would deliberate these concerns between conference sessions.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 99-209 to an appropriate committee as determined by the Conference Chairman, and further recommended that this committee be established by October 1, 2001 and that it include members of enforcement in addition to members of the current time temperature committee, and that a report be provided to the Spring 2002 Executive Board meeting.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

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ISSUE NUMBER: 99-213

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter XV.07B. *[Ed. note: Reference based on new Chapter XV. which was adopted at 1998 annual meeting in San Diego.]*

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XV.07B. by adding new subsection (2):

B. Shall ensure that all microbiological assays of end-point samples of shellstock:

(1) Are analyzed by a laboratory, which has been evaluated and approved pursuant to the requirements of Chapter III, using an NSSP-approved method with a sensitivity equivalent to or greater than a twelve-tube single dilution MPN test method;

(2) If the twelve-tube single dilution MPN is used, a value of 780 FC is substituted for the indeterminate score of >248 FC.

~~(2)~~ **(3)** Sample size consists of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish).

~~(3)~~ **(4)** Samples are collected at locations within the depuration unit that are considered to be the most compromised as regards shellfish activity, based on the sampling plan contained in the Depuration Plant Operations Manual.

PUBLIC HEALTH SIGNIFICANCE: There are many advantages for using the twelve-tube single dilution MPN test including increased sensitivity in the ranges in which depuration end-points typically fall. However, when an indeterminate score of >248 is obtained, an appropriate value needs to be substituted. The substitute value of 780 FC is one that affects the P 90 in such a way that the conditional protocol will be triggered. When in the conditional protocol, the depuration process is considered unverified and there are other sampling requirements for additional control.

COST INFORMATION: Insignificant.

ACTION BY 1999 TASK FORCE II: Recommended referral of Issue 99-213 to appropriate committee as determined by the Conference Chairman.

ACTION BY 1999 GENERAL ASSEMBLY: Adopted recommendation of 1999 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2000 DEPURATION/WET STORAGE COMMITTEE: Recommended referral of Issue 99-213 to the Depuration/Wet Storage Committee with the recommendation that a qualified statistician provide guidance in how to utilize indeterminate scores and report back to the Committee at the next meeting.

ACTION BY 2000 TASK FORCE II: Recommended adoption of 2000 Depuration Wet Storage Committee recommendations.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2001 MICROBIOLOGY COMMITTEE: **Note: the 2001 Microbiology Committee met and provided the following recommendation to the 2001 Depuration Committee**: (1) The Depuration Committee should recommend that FDA Interpretation No. 99-XV-03L-100 be followed for alteration of indeterminate MPN values from depurated shellfish. (2) The Depuration Committee might want to consider the consequences to process verification of the new method for calculation of the 90th percentile value. (3) Information in the FDA interpretation should be formally incorporated into the Model Ordinance, perhaps as an intact appendix, as the document is well written and contains illustrative examples**.**

ACTION BY THE 2001 DEPURATION COMMITTEE: Recommended adoption of the following recommendation:

1.) Insert the into the Model Ordinance the following language, which is editorialized for ease of reading, from FDA Interpretation No. 99-XV-03L-100:

XV .03 L. (1) (e)

For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.

2.) Incorporate the content of FDA Interpretation No 99-XV-03L-100 in the Guidance Section of the Guide for the Control of Molluscan Shellfish.

3.) Make recommendation #1 above effective immediately.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 99-213 as recommended by the 2001 Depuration Committee, Recommendation 1 for Satisfactory Compliance and Recommendation 2 for the Guidance document.

The Task Force further recommended an effective date of September 1, 2001 and expedited FDA review.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

* * *

ISSUE NUMBER: 99-215

SPECIFIC REFERENCE: 1999 Model Ordinance Definition (30); Chapter XV.03C.; Chapter XV.07 *[Ed. note: Chapter XV. references based on new language which was adopted at the 1998 annual meeting.]*

TEXT OF ISSUE:

REQUESTED ACTION #1: Modify 1999 Model Ordinance Definition (30):

(30) Depuration or depurate means the process of reducing the **contaminants, either** pathogenic organisms **or marine biotoxins,** that may be present in shellstock by using a controlled aquatic environment as the treatment process.

REQUESTED ACTION #2: Modify 1999 Model Ordinance Chapter XV.03D., (1998 Summary of Actions, page 104), by adding new paragraph D. :

D. If depurating for marine biotoxins, verify that the disinfection system process produces process seawater with no detectable levels of biotoxins.

REQUESTED ACTION #3: Modify 1999 Model Ordinance Chapter XV.03, (1998 Summary of Actions, page 104), by adding new paragraph E.:

E. Install a process water disinfection system. Any residuals must meet the requirements of the Food Additive Regulations.

REQUESTED ACTION #4: Modify 1999 Model Ordinance Chapter XV.07, (1998 Summary of Actions, page 107), by adding new paragraph C.:

C. For marine biotoxin depuration, performance verification to develop a depuration plant performance standard of nondetectable for marine biotoxins.

PUBLIC HEALTH SIGNIFICANCE: Red tide has been a consistent problem in the West Coast of Florida. Many shellfish harvesters and aquaculture lease holders have not been able to harvest their crops due to extended area closure. Research and nature have shown the possibility of effectively depurating marine biotoxins from molluscan shellfish. Ongoing research in New Zealand, Australia and the United States have the task of fine tuning the parameters, i.e. initial depuratable load, end-product standards, process parameters, etc., need to assure that the product is safe to the consumer before it is released into the marketplace. As with pathogenic contamination, the State Authority will follow strict guidelines before licensing any individual or firm to be able to depurate any product. Also the Authority will monitor very closely all activities in the firm by monthly inspections and document reviews, no batch shall be released without end-product meeting the pre-set standards.

COST INFORMATION: Not available.

ACTION BY 1999 TASK FORCE II: Recommended referral of Issue 99-215 to appropriate committee as determined by the Conference Chairman with following instructions: Charge this committee not to deal with this issue until pending research has been completed.

ACTION BY 1999 GENERAL ASSEMBLY: Adopted recommendation of 1999 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2000 DEPURATION/WET STORAGE COMMITTEE: Recommended No Action on Issue 99-215. Rationale: There is insufficient evidence to merit moving forward with guidelines for the depuration of biotoxins. The committee also suggested there is a need for additional research in this area.

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 99-215 to appropriate committee as determined by Conference Chairman with the following instructions: Charge this committee not to deal with this issue until pending research has been completed.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 99-215 to appropriate committee as determined by Conference Chairman, and further recommended that the data from pending research be completed.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

* * *

ISSUE NUMBER: 00-101/201/301 (hereinafter referred to as **Issue 00-201**)

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter II.

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter II. by adding new Section @.04:

Chapter II. Risk Assessment and Risk Management.

***@*.04 *Vibrio vulnificus* Risk Management**

A. Risk Management Plan

(1) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state, the Authority shall develop and implement a *Vibrio vulnificus* risk management plan. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

(2) The plan may include the following elements and shall define the administrative procedures

and resources necessary to accomplish (i.e., establish and maintain) them;

(a) Education/Consumer intervention;

(b) Pre-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock; and

(c) Post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock.

(3) The plan shall include controls and interventions that are designed to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported in core states from the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 2005 and by 60 percent by 2007. The rate of illness shall be calculated as the number of illnesses divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data. Core states shall be Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama. The baseline data for measuring illness reduction shall be the reported illnesses in the core states for the period 1996 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2001 data. See §B.(1) below.

(4) At a minimum, the plan shall include the following controls and interventions:

(a) Education/Consumer intervention - Implementing ~~of~~ those portions of the ISSC Education/Consumer Intervention Plan that are relevant to the state;

(b) Pre-harvest Controls - Based on the results of the annual FDA state shellfish program evaluation, assuring that all certified dealers comply with the time/temperature requirements contained in VIII.03, IX.05, XI.01A.(3), XII.01A.(3), XIII.01A.(3), and XIV.01A.(3). *[Ed. note: see proposed language for XI.01A.(3), XII.01A.(3), XIII.01A.(3), and XIV.01A.(3) in Issue 00-208.]*

(c) Post-harvest Controls

(i) Providing assistance, as necessary, for the further study of dockside icing to investigate its effects on shelf-life and variations in the effectiveness of the method as a result of seasonal and regional differences;

(ii) Implementing dockside icing requirements if the study results are favorable and illness reduction targets are not met as described in §(5) below;

(iii) Supporting, as necessary, the commercialization of existing post-harvest technologies and the development of new technologies;

(iv) Providing incentives to add refrigeration capacity to harvest vessels; and

(v) Selecting and preparing for the implementation of one or more of the controls contained in II.@.04A.(6), in case such implementation becomes necessary, as described in that paragraph.

(5) If the illness reduction goal contained in II.@.04A.(3) is less than 25 percent by the end of Year 4 (2004), the goal must be reassessed through a thorough review of the more intensive epidemiological investigations of illnesses for years 2001-2004.

[Submitter's note: The details of this more intensive epidemiological investigation are being discussed by the Vibrio Management Committee (VMC). Final recommendations will be made available following the VMC meeting on June 13 and 14.]

(6) Affected states must implement one or more of the following control strategies on January 1, 2008, if the illness reductions fail to meet the requirements of §(5) above.

[*Submitter's note: The Committee is discussing multiple options for appropriate control strategies. They include:*

(a) Labeling oysters when water temperatures reach a certain level (65? Fahrenheit is being discussed);

(b) Requiring post-harvest treatment when water temperatures exceed a certain level (65? Fahrenheit is being discussed);

(c) Closing growing areas when water temperatures exceed a certain level (65? Fahrenheit is being discussed);

(d) Labeling shellfish, "For shucking and cooking only" based on Vibrio vulnificus levels in meats;

(e) Requiring post-harvest treatment based on levels of Vibrio vulnificus in meats at harvest;

(f) Closing growing areas based on Vibrio vulnificus levels in meats at harvest;

(g) Labeling oysters "For shucking and cooking only" during certain months;

(h) Requiring post-harvest treatment during certain months;

(i) Closing certain shellfish growing areas during certain months.

Submitter's note: Final recommendations will be made available following the VMC meeting on June 13 and 14.]

B. Epidemiological Plan

(1) Core states referenced in §A. above will administer a survey to determine the Vibrio vulnificus disease reporting practices in each state for the period 1996-1999. The development and implementation plan for the survey will be initiated through the ISSC with participation of state public health officers, epidemiologists and others as determined. Continued surveillance will be necessary to indicate changes to reporting practices during 2000-2007. This is fundamental to establishing the illness baseline as described in §A.(3) above and in tracking future illness report data.

(2) Beginning in calendar year 2001, a new shellfish-borne Vibrio vulnificus disease investigation team will rapidly investigate any case of etiologically confirmed shellfish-borne Vibrio vulnificus septicemia illnesses in core states. This team will gather customary epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne Vibrio vulnificus septicemia illnesses. The ISSC will assist in initiating this team.

PUBLIC HEALTH SIGNIFICANCE: This plan is aimed at reducing exposure to *Vibrio vulnificus*, especially in at-risk populations. These controls, by potentially decreasing exposure, can in turn potentially reduce oyster-borne *Vibrio vulnificus* septicemia illnesses.

COST INFORMATION: Unknown.

ACTION BY 2000 VIBRIO MANAGEMENT COMMITTEE: Recommended adoption of 00-201 as substituted by the Vibrio Management Committee (VMC).

Text of Issue:
Modify Model Ordinance Chapter II., by adding Section @.04:

@.04 *Vibrio vulnificus* Risk Management

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* risk management plan.

(B) The plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The goal of the program will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported in core states (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) from the consumption of commercially harvested raw or undercooked oysters by 40 percent, collectively, by the end of 2005 and by 60 percent, collectively, by the end of 2007. The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from th e states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. The goal may be reevaluated prior to the year 2005 and adjusted in the event that new science, data or information becomes available.

(C) The plan shall also include identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent illness reduction goal not be achieved by 2007. This portion of the plan shall be completed no later than December 2006. The temperature and month-of the-year parameters identified in the following controls may be adjusted as needed to achieve the established illness reduction goal.

(1) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75? F;

(2) Subjecting all oysters to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75? F;

(3) Closing shellfish growing areas when the Average Monthly Maximum Water

Temperature exceeds 75? F;
(4) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;
(5) Subjecting all oysters to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;
(6) Closing shellfish growing areas during the months of May through September, inclusive.

Modify the NSSP Guide for Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision).

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). At the 2000 annual meeting the voting delegates will be asked to adopt the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia. The goal is to reduce those illnesses reported in core states (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) from the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 2005 and by 60 percent by the end of 2007. The Core States are the states that have consistently reported *Vv* cases since 1995. The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. This adjustment will be performed in consultation with statisticians and epidemiologists from core states and federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the core states for the period 1996 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2001 data. The formula for calculating for the rate of illness is as follows:

$$\frac{\left[\frac{\text{(number of cases) x (CDC adjustment factor)}}{\text{population}}\right]}{\text{production}}$$

The VMC members will include, at a minimum, industry and state shellfish control authority representatives from *Vibrio vulnificus* Illness Source and Core States, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Core states are Florida, Texas, California, Louisiana, Georgia, South Carolina and Alabama. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

The VMC will meet at least annually to develop and approve work plans and review progress. The first plan will be in place for a one-year period, followed by three biennial plans. The first work plan and progress review period will be from January 2001 to December 31, 2001. The next work plan period will be from January 1, 2002 to December 31, 2003, January 1, 2004 to December 31, 2005; then January 1, 2006 to December 31, 2007.

Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The biennial work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw oysters. The ISSC Education Committee and the *Vibrio vulnificus* Education Subcommittee will assist in the development and oversight for this program.

(i) The Consumer Education Program will focus educational efforts in the Core States. The Education Program will make educational materials available to states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Periodic administration of Behavior Risk Factor State Surveys (BRFSS) and other survey assessments at the state level shall be explored as a means of assessing the effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state;

(c) Creation of a shellfish-borne *Vibrio vulnificus* disease investigation team that will be available to assist in collection of epidemiological information associated with confirmed shellfish-borne *Vibrio vulnificus* septicemia illness. This team will assist in gathering customary epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses. A small ISSC team with recognized epidemiological officers will assist in rapid investigation of any case. This team will work cooperatively with existing local, state and federal disease investigation programs.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e.hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) To encourage implementation of post harvest controls the Conference will pursue options such as SBA low interest loans; revolving loans; cost sharing; demonstration projects; state-industry partnerships; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a source state by the end of the third year (December 31, 2003). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, the VMC will pursue additional incentives to achieve the goals.

(f) A VMC compilation and review of the data on rates of illness will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC

shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire conference.

(g) A VMC evaluation of the effectiveness of reduction efforts will be conducted at the end of the fifth year (December 31, 2005). The evaluation will determine whether the 40 percent, 5 year illness reduction goal or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2006 - 2007 work plan to assure achievement of the 60 percent illness reduction goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

PUBLIC HEALTH SIGNIFICANCE: The purpose of the National Shellfish Sanitation Program is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of foodborne hazards. Complete elimination of illness is difficult to attain but public health programs should be designed to provide the greatest level of public health protection possible. The vision of public health officials must focus on maximizing protection with the most practical public health measures available. This plan is designed to assure a significant reduction in *Vibrio vulnificus* septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, mandatory harvesting or processing controls.

COST INFORMATION: Unknown.

In addition the Committee recommended:

(1) Issue 00-201 become effective October 1, 2000; and the requirement for the *Vibrio vulnificus* Management Plans specified in Section .04A. be developed by these states by April 1, 2001;
(2) Establish a new VMC technical subcommittee that would come up with a list of research and market-related questions and needs relative to the design of a PHT incentive program; and
(3) Ensure that the VMC establishes and performs all necessary evaluations of goals, tasks, performance measures, assessment measures and data collection elements contained in the new Model Ordinance Section @.04 *Vibrio vulnificus* Risk Management, and in the *Vibrio vulnificus* Management Guidance Document.

ACTION BY 2000 TASK FORCE II: Recommended adoption of Issue 00-201 as substituted by the Vibrio Management Committee (VMC) and further amended as follows:

TEXT OF ISSUE:

Modify Model Ordinance Chapter II. By adding Section @.04:

@.04 *Vibrio vulnificus* Risk Management **for Oysters**.

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* risk management plan.

(B) The plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. **The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses**. The goal of the Vibrio Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses, reported in core states, ~~which may include (Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama) to~~

~~be determined by the VMC after a thorough review of statistical and epidemiological information~~ from the consumption of commercially harvested raw or undercooked oysters by 40 percent, collectively, by the end of 2005 and by 60 percent, collectively, by the end of 2007. **The core states include Florida, Texas, California, Louisiana, Georgia, South Carolina, and Alabama.** T**he list of core states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate .** The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. The goal may be reevaluated prior to the year 2005 and adjusted in the event that new science, data or information becomes available.

(C) The plan shall also include identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent ~~illness~~ **rate of illness** reduction goal not be achieved by 2007. This portion of the plan shall be completed no later than December 2006. The temperature and month-of the-year parameters identified in the following controls may be adjusted as needed to achieve the established illness reduction goal.

(1) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75?F;

(2) Subjecting all oysters **intended for the raw, half-shell market** to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75?F;

(3) Closing shellfish growing areas **for the purpose of harvest of oysters intended for the raw, half-shell market** when the Average Monthly Maximum Water Temperature exceeds 75?F;

(4) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;

(5) Subjecting all oysters **intended for the raw, half-shell market** to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;

(6) Closing shellfish growing areas **for the purpose of harvesting oysters intended for the raw, half-shell market** during the months of May through September, inclusive.

Modify the NSSP Guide for the Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision.)

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). At the 2000 annual meeting the voting delegates will be asked to adopt the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia. The goal is to reduce ~~those~~ **the rate of** illness reported in core states ~~from~~ **due to** the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 2005 and by 60 percent by the end of 2007. The Core States are the states that have consistently reported *Vibrio vulnificus* cases since 1995. **The list of core states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate.** The rate of illness shall be calculated as the number of illnesses adjusted for population and rate of reporting divided by the production of oysters from the states bordering the Gulf of Mexico, based on National Marine Fisheries Service landing data verified by Silver Spring, Maryland, headquarters. This adjustment will be performed in consultation with statisticians and epidemiologists from core states and federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the core states for the period 1996 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2001 data. The formula for calculating the rate of illness is as follows:

$$\frac{\text{(number of cases) x (}\sout{\text{CDC}}\ \textbf{illness reporting}\ \text{adjustment factor)}}{\text{population}}$$

production

The VMC members will include, at a minimum, **balanced representation from** industry and state shellfish control **authorities** from *Vibrio vulnificus* Illness Source and Core States, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Core states are Florida, Texas, California, Louisiana, Georgia, South Carolina and Alabama **or those states determined to be appropriate after a thorough review of epidemiological and statistical data.** Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

Recognizing the increasing importance and roles for the VMC, the Committee leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2000 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office should be for (2) years.

The VMC will meet at least annually to develop and approve work plans and review progress. The first plan will be in place for a one-year period, followed by three biennial plans. The first work plan and progress review period will be from January 2001 to December 31, 2001. The next work plan period will be from January 1, 2002 to December 31, 2003, January 1, 2004 to December 31, 2005**;** then January 1, 2006 to December 31, 2007.

Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver **a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The biennial work plan structure, outlined below,** provides adaptive management and assures consistent progress towards the illness reduction goals.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Education Committee and the *Vibrio vulnificus* Education Subcommittee will assist in the development and oversight for this program.

(i) The Consumer Education Program will focus educational efforts in the Core States. The Education Program will make educational materials available to states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Periodic administration of Behavior Risk Factor State Surveys (BRFSS) and other survey assessments at the state level shall be explored as a means of assessing the effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.

(c) Creation of a shellfish-borne *Vibrio vulnificus* disease investigation team that will be available to assist in collection of epidemiological information associated with confirmed shellfish-borne *Vibrio vulnificus* septicemia illness. This team will assist in gathering customary epidemiological information as well as the level of awareness of risk in those who have suffered etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses. A small ISSC team with recognized epidemiological officers will assist in rapid investigation of any case. This team will work cooperatively with existing local, state and federal disease investigation programs.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e.hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) To encourage implementation of post harvest controls the Conference will pursue options such as ~~SBA low interest loans; revolving loans; cost sharing; demonstration projects; state-industry partnerships;~~ **market development;** FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a source state by the end of the third year (December 31, 2003). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, ~~the VMC will pursue additional incentives to achieve the goals.~~ **the VMC will investigate and report their findings as to why the goal was not reached.**

(f) The VMC will develop a list of issues relating to public health, various technologies; including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

~~(f)~~**(g)** A VMC compilation and review of the data on rates of illness will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire conference.

~~(g)~~**(h)** A VMC evaluation of the effectiveness of reduction efforts will be conducted at the end of the fifth year (December 31, 2005). The evaluation will determine whether the 40 percent, 5 year ~~illness reduction~~ goal **to reduce the rate of illness** or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2006 - 2007 work plan to assure achievement of the 60 percent ~~illness~~ reduction **in the rate of illness** goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

PUBLIC HEALTH SIGNIFICANCE: The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of foodborne hazards. Complete elimination of illness is difficult to attain but public health programs should be designed to provide the greatest level of public health protection possible. The vision of public health officials must focus on maximizing protection with the most practical public health measures available. This plan is designed to assure a significant reduction in *Vibrio vulnificus* septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, mandatory harvesting or processing controls.

COST INFORMATION: Unknown.

The Task Force further recommended adoption of the 2000 Vibrio Management Committee recommendations # 1, 2, and 3.

ACTION BY 2000 GENERAL ASSEMBLY: The 2000 General Assembly referred Issue 00-201 to appropriate committee as determined by the Conference Chairman.

ACTION BY USFDA: Concurred with Conference action.

ACTION BY 2001 VIBRIO VULNIFICUS SUBCOMMITTEE: Recommended adoption of Issue 00-201 as amended and presented in the 2001 Issue packet:

TEXT OF ISSUE:

Modify Model Ordinance Chapter II. By adding Section @.04:

@.04 *Vibrio vulnificus* Risk Management for Oysters.

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* risk management plan.

(B) The Source State's *Vibrio vulnificus* management plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by ~~core reporting states, collectively~~ California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, ~~collectively, by the end of~~ for years 2005 and 200~~5~~6 (average) and by 60 percent for years 2007 and ~~collectively, by the end of~~ 200~~7~~8 (average) ~~from the current~~ rate of 0.306/million from the average illness rate for the years 1995 - 1999 of 0.306/million~~. The core reporting states include Florida, Texas, California, and Louisiana.~~ The list of ~~core reporting~~ states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 200~~5~~6 and adjusted in the event that new science, data or information becomes available.

(C) The Source States's *Vibrio vulnificus* management plan shall also include identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 200~~7~~8. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the plan shall be completed no later than December 200~~6~~7. The temperature and month-of the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state

basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(1) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75?F;

(2) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75?F;

(3) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75?F;

(4) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;

(5) Subjecting all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;

(6) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Modify the NSSP Guide for the Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision.)

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus* subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces will review the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in ~~core reporting states~~ California, Florida, Louisiana and Texas due to the consumption of commercially harvested raw or undercooked oysters by 40 percent by the end of 200~~5~~6 and by 60 percent by the end of 200~~7~~8. ~~The Core Reporting States are Louisiana, California, Florida, and Texas. The list of core reporting.~~ The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and epidemiologists from ~~core reporting states~~ California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the ~~core reporting states~~ California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 200~~1~~2 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas) ~~Core Reporting State~~, the following will apply:

(a) Illness cases counted are those reported by ~~Core Reporting States~~ California, Florida, Louisiana and Texas;
(b) Each illness case is recorded under the state that reports it;
(c) Each case is not counted more than once; and
(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.

The formula for calculating the rate of illness is as follows:

$$\frac{\text{(number of cases)}}{\text{population}}$$

The ~~VMC~~ Vv subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States ~~and Core Reporting States~~ California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. ~~Core reporting states are Florida, Texas, California, and Louisiana, or those states determined to be appropriate after a thorough review of epidemiological and statistical data.~~ Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met.

Recognizing the increasing importance and roles for the, the Committee leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 200~~0~~1 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office ~~should~~ shall be for (2) years.

The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. ~~The first plan will be in place for a one-year period, followed by three biennial plans.~~ A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will ~~be from January 2001 to December 31, 2001.~~ cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. ~~The next work plan period will be from January 1, 2002 to December 31, 2003, January 1, 2004 to December 31, 2005; then January 1, 2006 to December 31, 2007.~~

Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The ~~biennial~~ annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:

- ?? increased educational efforts,
- ?? limited harvest restriction,
- ?? reduction in time from harvest to refrigeration,
- ?? phased-in post-harvest treatment requirements, or
- ?? other equivalent controls.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will ~~assist~~ evaluate Year 2001 survey results ~~will be~~ and compared ~~to~~ them with the Year 2003 or 2004 survey results to ~~demonstrate that~~ determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from Vv; and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption. ~~in the development and oversight for this program~~.

(i) The Consumer Education Program will focus educational efforts ~~in the Core Reporting States~~ California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state;

(c) Creation of a ~~A committee~~ working group ~~will be created~~ to work cooperatively with local, state, and federal agencies and ~~program~~ programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this ~~subcommittee~~ working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) Pursuit of ISSC options ~~To encourage implementation of post harvest controls the Conference will pursue options~~ such as industry education and communication; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 20 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a ~~source state~~ Source State by the end of the third year (December 31, 200~~3~~4. The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 20 percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.

(f) Development by the VMC of ~~The VMC will develop~~ a list of issues relating to public health, various technologies~~;~~ including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

(g) Provision for a ~~A~~ VMC compilation and review of the data on rates of illness which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire ~~conference~~ membership.

(h) Provision for a ~~A~~ VMC evaluation of the effectiveness of reduction efforts which will be conducted at the end of the fifth year (December 31, 200~~5~~6). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 200~~6~~7 - 200~~7~~8 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

(i) Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04c, the Vv Subcommittee will be requested to provide guidance.

PUBLIC HEALTH SIGNIFICANCE: The purpose of the National Shellfish Sanitation Program is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State Shellfish Programs. This includes protection of the public health by reducing the prevalence of foodborne hazards. Complete elimination of illness is difficult to attain but public health programs should be designed to provide the greatest level of public health protection possible. The vision of public health officials must focus on maximizing protection with the most practical public health measures available. This plan is designed to assure a significant reduction in *Vibrio vulnificus* septicemia illnesses through a combination of consumer education, processing incentives and, if necessary, mandatory harvesting or processing controls.

COST INFORMATION: Unknown.

ACTION BY 2001 VIBRIO VULNIFICUS SUBCOMMITTEE: Recommended the following changes to Issue 00-201 at the July 22, 2001 subcommittee meeting:

TEXT OF ISSUE:

Modify Model Ordinance Chapter II. By adding Section @.04:

@.04 *Vibrio vulnificus* Risk Management for Oysters.

(A) For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* management plan.

(B) The Source State's *Vibrio vulnificus* management plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. ~~The Plan shall include, at a minimum, the ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses~~. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 - 1999 of 0.306/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data or information becomes available.

(C) The Source States's *Vibrio vulnificus* management plan **shall include, at a minimum:**
(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;
(2) A process to collected standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;
(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses;
(4) Identification and preparation for achieving a goal of post-harvest treatment capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest treatment will include the capacity of all operational plants and the capacity of plants under construction;
(5) Identification and preparation for implementation of required post harvest treatment capacity of 50% of all oysters intended for the raw, half-shell market during the months of May

through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest treatment will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in .04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest treatment, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and

(6) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the plan shall be completed no later than December 2007. The temperature and month-of the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(a) Labeling all oysters, "For shucking by a certified dealer," when the Average Monthly Maximum Water Temperature exceeds 75?F;
(b) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75?F;
(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75?F;
(d) Labeling all oysters, "For shucking by a certified dealer," during the months of May through September, inclusive;
(e) Subjecting all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive;
(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Modify the NSSP Guide for the Control of Molluscan Shellfish by adding the following Guidance Document (numbering to be determined at time of publication of the next revision.)

***Vibrio vulnificus* Management Guidance Document**

***Vibrio vulnificus* Management**

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus* subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces will review the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in California, Florida, Louisiana and Texas due to the consumption of commercially harvested raw or undercooked oysters ~~by 40 percent by the end of 2006 and by 60 percent by the end of 2008.~~ **by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995- 1999 of 0.306/million.** The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and epidemiologists from California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2002 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas), the following will apply:

(a) Illness cases counted are those reported by California, Florida, Louisiana and Texas;
(b) Each illness case is recorded under the state that reports it;
(c) Each case is not counted more than once; and
(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.

The formula for calculating the rate of illness is as follows:

$$\frac{\text{number of cases}}{\text{population}}$$

The V.v. subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Etiologically confirmed means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met

Recognizing the increasing importance and roles for the, the Committee leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2001 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office shall be for (2) years.

The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:

?? increased educational efforts,
?? limited harvest restriction,
?? reduction in time from harvest to refrigeration,
?? phased-in post-harvest treatment requirements, or
?? other equivalent controls.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program's objectives will be 1) to increase the target audience's awareness that eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will evaluate Year 2001 survey results and compare them with the

Year 2003 or 2004 survey results determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from Vv; and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption.

(i) The Consumer Education Program will focus educational efforts **in** California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.

(c) Creation of a working group to work cooperatively with local, state, and federal agencies and programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) Pursuit of ISSC options such as industry education and communication; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat ~~20~~ **25** percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the ~~20~~ **25** percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.

(f) Development by the VMC of a list of issues relating to public health, various technologies~~,~~ including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

(g) Provision for a VMC compilation and review of the data on rates of illness, which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire membership.

(h) Provision for a VMC evaluation of the effectiveness of reduction efforts, which will be conducted at the end of the fifth year (December 31, 2006). The evaluation will determine whether the 40

percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2007 - 2008 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

(i) Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04~~c~~**(C)**, the V.v. Subcommittee will be requested to provide guidance.

The *Vibrio vulnificus* Subcommittee further recommended the following:

1) Request the Executive Board request FDA to meet with the Irradiation petition submitter to establish a timetable under which FDA will review the petition.

2) Request the Executive Board request FDA and the state of California seek additional funding to increase the education of at-risk consumers in California, particularly in southern California,

3) Recommended that the Chairman appoint a committee to develop further guidance language for implementation of .04 (C) (1)-(5).

4) Recommended adoption of an effective date of October 1, 2001, and further recommended an expedited review by FDA.

ACTION BY 2001 VIBRIO MANAGEMENT COMMITTEE: Recommended adoption of the V. vulnificus Subcommittee Report recommendations.

ACTION BY 2001 TASK FORCE II: Recommended adoption of 2001 Vibrio Management Committee Report recommendations.

The Task Force further recommended the Executive Board Chairman appoint an appropriate committee which shall develop a threshold for adoption of *Vibrio vulnificus* management plans (.04)(A), and for development of an exit strategy for source states.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action. Provided comments. See Attachment at end of Task Force II.

* * *

ISSUE NUMBER: 00-204

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII.02

TEXT OF ISSUE:

REQUESTED ACTION #1: Modify 1999 Model Ordinance Chapter VIII.02, by adding new paragraph F.:

F. The harvester shall place shellstock under proper temperature control within 2 hours after bring shellstock to dockside.

REQUESTED ACTION #2: Modify 1999 Model Ordinance Chapter IX.02C., by adding new subparagraph (2):

C. The dealer shall:
(1) Inspect incoming ... required in this Chapter;
(2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or

when the dealer is also the harvester, when shellstock reaches the facility dock;
~~(2)~~ **(3)** Ensure that shellstock ... such as loading docks;
~~(3)~~ **(4)** Ensure that shucked shellfish ... or less; and
~~(4)~~ **(5)** Ensure that frozen shellfish remain frozen.

PUBLIC HEALTH SIGNIFICANCE: The wording in new paragraph VIII.02F. and new subparagraph IX.02C.(2) establishes temperature control time requirements for shellstock products from the time the harvester brings the shellstock to the dock or it is placed under temperature control in the dealer's facility. Time required for placing shellstock under temperature control after arrival at dockside is not addressed in the Model Ordinance.

COST INFORMATION: N/A

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 00-204 to appropriate committee as determined by Conference Chairman.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 TIME-TEMPERATURE COMMITTEE: Recommended No Action. Rationale: This change would create several conflicts with the manual and creates a need for clarifications.

ACTION BY 2001 TASK FORCE II: Recommended adoption of the Time-Temperature Committee recommendation.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Did not concur with Conference action. Recommended Issue 00-204 be returned to appropriate committee for further consideration. Provided comments. See Attachment at end of Task Force II.

ACTION BY ISSC EXECUTIVE BOARD: Recommended referral of Issue 00-204 to appropriate committee as determined by the Conference Chairman.

* * *

ISSUE NUMBER: 00-205

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter VIII.03

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter VIII.03:

VIII.03. Shellstock Temperature Control

Note: The Authority shall select only one of the following options for implementation in its state. **The time-temperature matrix for each of the options applies only to the original harvester or harvester/dealer of shellstock for purposes of handling and transporting shellstock to the first point of processing or packing.**

PUBLIC HEALTH SIGNIFICANCE: The time-temperature matrix options were adopted as a compromise between public health principles of cooling shellstock to prevent the multiplication of pathogenic bacteria and the practical difficulty for harvesters to cool shellstock on vessels and between the harvest site and the packing facility. Once shellstock reaches the first dealer, it should be iced or placed in a cooler at 45º Fahrenheit ambient temperature to reduce the internal temperature to 50º Fahrenheit as soon as possible in order to prevent the growth of pathogenic bacteria. This is consistent with standard operating practices that are used for the safety of other potentially hazardous foods.

The time-temperature matrix options are not supported by food safety guidelines in the "Fish and Fisheries Products Hazards and Controls Guide: Second Edition" of the US Food and Drug Administration. They contradict requirements of 21 CFR, Part 123, for assuring safe processing of fish and fishery products. The contradiction with 21 CFR, Part 123, can be eliminated by limiting the applicability of the time-temperature matrix options to activities associated directly with harvesting.

COST INFORMATION: Unknown.

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 00-205 to appropriate committee as determined by Conference Chairman. Task Force further recommended that the issue be sent to same committee as Issue 00-204.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 TIME-TEMPERATURE COMMITTEE: Recommended No Action. Rationale: This change conflicts with the manual and existing interpretations**.**

ACTION BY 2001 TASK FORCE II: Recommended adoption of the 2001 Time-Temperature Committee recommendation.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Did not concur with Conference action. Recommended Issue 00-205 be returned to appropriate committee for further consideration. Provided comments. See Attachment at end of Task Force II.

ACTION BY ISSC EXECUTIVE BOARD: Recommended referral of Issue 00-205 to appropriate committee as determined by the Conference Chairman.

* * *

ISSUE NUMBER: 00-206

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter IX.05A. and B.

TEXT OF ISSUE:

REQUESTED ACTION: The appropriate ISSC committee is requested to examine measures to improve the assurance of safety of shellfish by proper temperature control during shipping by common carriers.

A possible solution is suggested by the following changes in the 1999 Model Ordinance:

IX.05 Shipping Times.
A. Shipping Time is No More Than Four Hours. ...

(5) When a dealer contracts with a common carrier to transport shellfish and relies on mechanical refrigeration for temperature control, the dealer shall require the common carrier to assure that the conditions of shipment in §A.(2) of this section are met.

B. Shipping Time is Greater than Four Hours. ...

(7) When a dealer contracts with a common carrier to transport shellfish and relies on mechanical refrigeration for temperature control, the dealer shall require the common carrier to assure that the conditions of shipment in §B.(1)(a) of this section are met.

PUBLIC HEALTH SIGNIFICANCE: The FDA National Shellfish Standard, Stanley Ratcliffe, advised west coast state standardization officers at a training session in Tacoma, Washington, in February 1999 that the shipping controls in Chapter IX.05 do not apply when shellfish is shipped by common carriers. Shipping controls could better be assured if dealers specified proper shipping conditions in contracts or other written agreements with common carriers. Companies shipping other types of food by common carriers frequently stipulate shipping conditions.

Temperature control is a preventative measure to assure shellfish safety at any critical control point where pathogenic bacteria could multiply to hazardous levels, according to guidelines in the "Fish and Fisheries Products Hazards and Controls Guide: Second Edition" of the US Food and Drug Administration. Although 21 CFR, Part 123, does not require the step of transporting fish and fishery products be considered a critical control point, shellfish safety requires that time-temperature controls be assured during shipping.

The shipping dealer is in the best position to assure shellfish safety during shipping. Regulators do not have the authority to make common carriers provide proper time-temperature controls when shellfish are in shipment. However, dealers could provide better assurance of shellfish safety when shipping by common carrier through the use of contractual specifications. This is especially important when shellfish are shipped great distances, out of the country, or directly to a retailer lacking training in the principles of HACCP.

COST INFORMATION: Unknown.

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 00-206 to appropriate committee as determined by Conference Chairman.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 TIME-TEMPERATURE COMMITTEE: Recommended No Action. Rationale: This issue is adequately addressed in the Model Ordinance.

ACTION BY 2001 TASK FORCE II: Recommended adoption of the Time-Temperature Committee recommendation.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Did not concur with Conference action. Recommended Issue 00-204 be returned to appropriate committee for further consideration. Provided comments. See Attachment at end of Task Force II.

ACTION BY ISSC EXECUTIVE BOARD: Recommended referral of Issue 00-206 to appropriate committee as determined by the Conference Chairman.

* * *

ISSUE NUMBER: 00-207

SPECIFIC REFERENCE: Model Ordinance Chapter XI.01C., page 78.

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XI.01C., page 78, by adding new subparagraph (4):

XI.01C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(3) If heat shock is used, ... after the heat shock process.

(4) When heat shocked shellstock is cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to 45? Fahrenheit (7.2 ? Centigrade) within two hours from time of heat shock.

PUBLIC HEALTH SIGNIFICANCE: The new language is provided to address activities not specifically included in the Model Ordinance.

COST INFORMATION: N/A

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 00-207 to appropriate committee as determined by Conference Chairman.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 COMMITTEE: No Committee Action.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 00-207 to an appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference Action.

* * *

ISSUE NUMBER: 00-211

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter X.06A.

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter X.06A., by adding new subsection (1):

X.06 Shucked Shellfish Labeling

A. Shellfish Labeling

(1) If a firm stores shucked shellfish under refrigerated conditions using in-plant reusable containers, the dealer shall mark or label each container with an in-plant processing code that will identify and maintain the integrity of each lot of shellfish.

Renumber subsequent subsections.

PUBLIC HEALTH SIGNIFICANCE: The recommended modification is editorial in nature to make the Model Ordinance more consistent with the language in Part II of the NSSP Manual of Operations.

COST INFORMATION: No cost.

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 00-211 to appropriate committee as determined by Conference Chairman.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 LABELING COMMITTEE: Recommended adoption of Issue 00-211 as amended. Modify Model Ordinance Chapter X .06A by adding new subsection (1) and renumbering subsequent sections as follows:

A. Shellfish Labeling

(1) If a firm stores shucked shellfish under refrigerated conditions using in-plant reusable containers, the dealer shall ~~mark or label each container with an in-plant processing code that will identify and maintain the integrity of each lot of shellfish.~~ **maintain lot integrity.**

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 00-211 as amended by the 2001 Labeling Committee.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 00-215

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter XI.02C.(2)(a) and (b); Chapter XI.02D.; Chapter XI.03A.(5); Chapter XI.03B.; Chapter XI.03C.; Chapter XI.03D.(1)(a); Chapter XI.03F.(1); Chapter XI.03G.(2); Chapter XI.03H.(1)(j) and (k); and corresponding references in Chapters XII., Chapter XIII., and Chapter XIV.

TEXT OF ISSUE:

REQUESTED ACTION #1: Modify 1999 Model Ordinance Chapter XI.02C.(2)(a) and (b):

XI.02C. Prevention of Cross Contamination.

(2) Employee practices.

(a) Where the same employee works in both the shucking and packing activities, the employee shall wash **and sanitize** his hands ...

(b) The dealer shall ... adequate handwashing **and sanitizing** facility.

REQUESTED ACTION #2: Modify 1999 Model Ordinance Chapter XI.02D.:

XI.02D. ~~Maintenance of~~ Hand Washing, Hand Sanitizing and Toilet Facilities.

The dealer shall provide:

(1) Handwashing and sanitizing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; *[Ed. note: Language moved from Chapter XI.03B.(4)(b). See Requested Action #4.]*

~~(1)~~ **(2)** Handwashing facilities with warm water at a minimum temperature of 110? Fahrenheit (43? Centigrade), dispensed from a hot and cold mixing or combination faucet~~, shall be provided.~~ **;**

~~(2) Sewage and liquid disposable wastes shall be properly removed from the facility.~~

(3) Drainage systems for proper removal of sewage and liquid disposable wastes from the facility;

(4) An adequate number of conveniently located toilets;

~~(4)~~ **(5)** ~~The dealer shall provide e~~ **E** ach toilet facility with a adequate supply of toilet paper in a suitable holder.

REQUESTED ACTION #3: Modify 1999 Model Ordinance Chapter XI.03A.(5):

XI.03A. Plants and Grounds.

~~(5) The dealer shall provide toilet room doors which are tight fitting, self closing and do not open directly into a processing area.~~ *[Ed. note: Language moved to Chapter XI.03D.(1)(a). See Requested Action #6.]*

REQUESTED ACTION #4: Modify 1999 Model Ordinance Chapter XI.03B.:

XI.03B. Plumbing and Related Facilities.

~~(5)~~ **(3)** The dealer shall provide at each handwashing facility: *[Ed. note: Typo correction.]*

(4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

~~(a) Cold and warm water at all sinks; and~~

~~(b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use;~~ *[Ed. note: Language moved to Chapter XI.02D.(1). See Requested Action #2.]*

(a) A supply of water that is adequate in quantity and pressure; and

(b) Cold and warm water at all sinks.

REQUESTED ACTION #5: Modify 1999 Model Ordinance Chapter XI.03C.:

XI.03C. Utilities.

(1) Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.

(2) Lighting.

(a) Lighting shall be provided in all processing and storage areas, all dressing, locker, and toilet rooms.

(b) Lighting is adequate to allow the intended operation to be performed.

REQUESTED ACTION #6: Modify 1999 Model Ordinance Chapter XI.03D.(1)(a):

XI.03D. Insect and Vermin Control.

(1) The dealer shall ... in his facility, including:

(a) Tight-fitting, self-closing doors, **including toilet room doors that do not open directly into a processing area;** *[Ed. note: Language moved from Chapter XI.03A.(5). See Requested Action #3.]*

REQUESTED ACTION #7: Modify 1999 Model Ordinance Chapter XI.03F.(1):

XI.03F. Equipment Construction for Non-food Contact Surfaces.

(1) The dealer shall used only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, ~~sanitized,~~ maintained, or replaced.

REQUESTED ACTION: #8: Modify 1999 Model Ordinance Chapter XI.03G.(2):

XI.03G. Cleaning Non-food Contact Surfaces.

(2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned **,** ~~and~~ maintained**, and stored** in a manner and frequency as necessary to prevent shellstock contamination.

REQUESTED ACTION #9: Modify 1999 Model Ordinance Chapter XI.03H.(1)(j) and (k):

XI.03H. Shellfish Storage and Handling.

(1) The dealer shall:

(j) Not commingle shellstock ... in the Authority's commingling plan~~; and~~ **.**

~~(k) Inspect incoming shipments and shall reject dead or inadequately protected shellstock.~~ *[Ed. note: Subsection (k) is a repeat of subsection (c).]*

REQUESTED ACTION #10: Modify 1999 Model Ordinance by making the above changes in corresponding references in Chapters XII., XIII., and XIV.

PUBLIC HEALTH SIGNIFICANCE: Most of the recommended changes are editorial in nature to make the Model Ordinance more consistent with the language in Part II of the NSSP Manual of Operations. However, some changes are provided to address activities or equipment needs not specifically included in the Model Ordinance.

COST INFORMATION: No cost.

ACTION BY 2000 TASK FORCE II: Recommended referral of Issue 00-215 to appropriate committee as determined by Conference Chairman.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 PROCESSING AND HANDLING COMMITTEE: Recommended No Action. Rationale: The submitter (FDA) wishes to withdraw Issue 00-215 and will provide guidance to clarify questions raised by the issue.

ACTION BY 2001 TASK FORCE II: Recommended adoption of the 2001 Processing and Handling Committee recommendation. Additional Rationale: FDA will determine if a new issue submission is needed.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 00-220

SPECIFIC REFERENCE: 1999 Model Ordinance Chapter XV.07B.(2)
[Ed. note: Reference is based on new language adopted in Task Force II amendment of Issue 98-228 at the 1998 annual meeting. If language in Issue 99-213 is adopted at the 2000 annual meeting, the reference will become XV.07B.(3).]

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XV.07(B)(2):

(2) ~~Sample size consists of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish).~~ **Sample size shall consist of a sufficient number of shellfish, selected at random from each batch to be tested, that will provide adequate tissue and**

liquid for the selected test method.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION: N/A

ACTION BY 2000 TASK FORCE II: Recommended Issue 00-220 be referred to the 2001 ISSC annual meeting. Rationale: Issue 00-220 did not meet the criteria outlined for the issues, which were to be deliberated at the 2000 ISSC Special Meeting.

ACTION BY 2000 GENERAL ASSEMBLY: Adopted recommendation of 2000 Task Force II.

ACTION BY 2001 TASK FORCE II: Recommended No Action. Rationale: Inadequate information provided to support the issue.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-201

SPECIFIC REFERENCE: Model Ordinance Reference XV .03 L. Process Verification.

TEXT OF ISSUE:

REQUESTED ACTION: Add new language to XV .03 L (2); new section (e)

The Dealer shall continuously:

(1) Perform process verification on a continuous basis according to the following protocol:

(a) Following completion…

(b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) harvest lots for each species depurated and for each restricted or conditionally restricted harvest area used.

(C) compare daily…

(d) If the depuration performance…

(2) Conditional Protocol Verification. If the depuration performance indicies…

(e) When in Conditional Protocol Verification due to a failure of an established harvest area to meet the above Indices for Depuration Plant Performance, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90^{th} percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive end product samples for each species depurated and for each restricted harvest area used.

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in .03L(1).

(iii) If either the geometric mean or the 90^{th} percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process shall remain in the Conditional Protocol Verification for this species from this particular harvest area until the above Indices of Depuration Plant Performance are attained.

(f) When in Conditional Protocol Verification due to the use of a new harvest area as the source of shellfish or if a new depuration process has generated less than 10 process batches of data, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90^{th} percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated

and for each restricted harvest area used.

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If 10 or more process batches of data have been collected and if these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in .03L(1).

(iii) If less than 10 process batches of data have been collected or either the geometric mean or the 90^{th} percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, from this particular harvest area, the process shall remain in the Conditional Protocol Verification for this species from this particular harvest area until 10 batches of data have been collected and the above Indices of Depuration Plant Performance are attained.

NOTE: SUBMITTER REQUESTS AN EFFECTIVE DATE OF AUGUST 1, 2001.
PUBLIC HEALTH SIGNIFICANCE: Guidance was not provided on how to fully utilize the triplicate end product assay data collected during Conditional Protocol Verification in the revised Chapter XV adopted in 1999. This provides clarification that when in Conditional Protocol Verification due to the utilization of a new harvest area or a new depuration plant, that the triplicate end product results should be recorded using the geometric mean value on a harvest lot basis. When an established area is in Conditional Protocol Verification, since a history of the area is known, the triplicate end product assay data are to be individually incorporated into the database maintained for each growing area.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended No Action. Rationale: Issue 01-201 was resolved by actions on 01-207 and 01-206

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-202

SPECIFIC REFERENCE: Model Ordinance Reference: Chapter XIV.03.A (5).

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter XIV.03A(5) by deleting 03.A(5)(c)(iv):

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility.

(b) All dry area floors shall be hard, smooth, easily cleanable; and

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage;

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;

(iii) Have sealed junctions between floors and walls to render them impervious to water; and

~~(iv) Are maintained in good repair.~~

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended No Action. Rationale: This section was previously removed from the Model Ordinance.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

** *

ISSUE NUMBER: 01-203

SPECIFIC REFERENCE: Model Ordinance Reference**:** Chapter XIV.03.J (4).

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter XIV.03.J by deleting section 03.J(4)(a) :

K. Supervision
(4) The dealer shall require:
~~(a) Supervisors to assure employees follow proper hygiene practices.~~
(a)~~(b)~~ Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant equipment clean-up
(ii) Rapid product handling; and
(iii) Shellstock protection from contamination.
(b)~~(c)~~ Employees
(i) to be trained in proper food handling and personal hygiene practices, and
(ii) to report any symptoms of illness to their supervisor.

PUBLIC HEALTH SIGNIFICANCE: None.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended No Action. Rationale: This section was previously removed from the Model Ordinance.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

** *

ISSUE NUMBER: 01-204

SPECIFIC REFERENCE: Model Ordinance Reference**:** NSSP Model Ordinance Chapter I.05.A

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter I.@02.C, as follows:

NSSP MO Requirements for Certification and Recertification:

Chapter I.@02 Dealer Certification

A. General

(1) A person requesting certification shall be subject to a comprehensive onsite inspection and meet the criteria in §B. or §C., as appropriate. The plant inspection shall be conducted by the state shellfish standardization inspector, using the appropriate inspection form, within the 120-day

period immediately prior to the issuance or renewal of the certification.

(2) Certification shall be given only to persons who meet the established requirements ~~established for certification~~.

B. Initial Certification

(1) Initial certification shall be given only to persons who meet the following standards ~~for certification~~:

(a) HACCP requirements

(i) A HACCP plan accepted by the Authority;

(ii) No critical deficiencies;

(iii) Not more than 2 key deficiencies;

(iv) Not more than 2 other deficiencies.

(b) Sanitation and additional Model Ordinance requirements

(i) No critical deficiencies;

(ii) Not more than 2 key deficiencies;

(iii) Not more than 3 other deficiencies.

(2) The initial certification shall include a compliance schedule to correct ~~the~~ any deficiencies ~~if necessary~~ not corrected by the dealer during the evaluation.

C. Renewal Of Certification

(1) A dealer shall make . . . .

~~(2)~~ The Authority shall not renew the certification for any dealer until the dealer ~~has~~:

(a) ~~Eliminated any critical deficiencies~~ Meets the requirements of §B.1(a) and §B.1(b). The number of deficiencies allowed under §B.1(a) and §B.1(b) shall include carry over deficiencies from an existing compliance schedule approved by the Authority and new deficiencies identified during the certification renewal inspection; and

~~(b) Agreed to a compliance schedule which carries forward into the next inspection no more than 2 key and 4 other deficiencies identified previous inspections.; and~~

~~(c)~~ (b) ~~Agreed~~ Agrees to a compliance schedule to address any new deficiencies not corrected by the dealer during the evaluation. ~~Addressed any new key or other deficiencies in a new or revised compliance schedule; and~~

~~(d) Met the requirements of §A.(2).~~

PUBLIC HEALTH SIGNIFICANCE: Current recertification requirements do not set an upper limit for the allowable number of new Key and Other deficiencies. Recertification requirements should be similar to initial certification requirements. Setting an upper limit on the total number deficiencies (new and carry over) under a compliance schedule at recertification would ensure that plants substantially meet the requirements of the NSSP when recertification is approved.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommend adoption of Issue 01-204 as amended:

Chapter I.@02 Dealer Certification.

A. General

(1) A person requesting certification shall be subject to a comprehensive onsite inspection and meet the criteria in §B. or §C., as appropriate. The plant inspection shall be conducted by the state shellfish standardization inspector, using the appropriate inspection form, within the 120-day period immediately prior to the issuance or renewal of the certification.

(2) Certification shall be given only to persons who meet the established requirements.

B. Initial Certification

(1) Initial certification shall be given only to persons who meet the following ~~standards~~ **requirements:**

(a) HACCP requirements

(i) A HACCP plan accepted by the Authority;

(ii) No critical deficiencies;

(iii) Not more than 2 key deficiencies;

(iv) Not more than 2 other deficiencies.

(b) Sanitation and additional Model Ordinance requirements
(i) No critical deficiencies;
(ii) Not more than 2 key deficiencies;
(iii) Not more than 3 other deficiencies.

(2) The initial certification shall include a compliance schedule to correct any deficiencies by the dealer during the ~~evaluation~~ **inspection**.

C. Renewal Of Certification

(1) A dealer shall make . . . .

~~(2)~~ The Authority shall not renew the certification for any dealer until the dealer

(a) Meets the requirements of §B.1(a) and §B.1(b). The number of deficiencies allowed under §B.1(a) and §B.1(b) shall include carry over deficiencies from an existing compliance schedule approved by the Authority and new deficiencies identified during the certification renewal inspection; and

(b) Agrees to a compliance schedule to address any new deficiencies not corrected by the dealer during the ~~evaluation~~ **inspection.**

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-205

SPECIFIC REFERENCE: Model Ordinance Reference**:** XV .02. A.(3)(a) Shellstock Washing.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter XV.02.A.(3):

.02 Sanitation

A. Safety of Water for Processing and Ice Production

(3) Shellstock washing

(a) Water from either a potable water supply, ~~or~~ a growing area in the approved classification, approved well, another approved source, or the restricted area at the time and place of harvest, shall be used to wash shellstock.

PUBLIC HEALTH SIGNIFICANCE: An approved well or another approved source of water should be allowed when washing dirt and debris from shellstock. Using an approved well or approved source of water will not degrade the quality of the shellstock during the washing process.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-205 as amended.

.02 Sanitation

A. Safety of Water for Processing and Ice Production

(3) Shellstock washing

(a) Water from either a potable water supply, a growing area in the approved classification, ~~approved well~~, ~~another approved source~~ **a saltwater well approved by the authority**, or the restricted area at the time and place of harvest, shall be used to wash shellstock.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-206

SPECIFIC REFERENCE: Model Ordinance Reference: XV.03 L.(1)(b) and XV.03 L.(2).

TEXT OF ISSUE:

REQUESTED ACTION: MODIFY Chapter XV.02L(1) and XV.03L(2):

.03 Other Model Ordinance Requirements
L. Process Verification:
(1) Perform process verification....
(a)…..
(b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90 th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each ~~restricted~~ harvest area used.....

(2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new ~~restricted~~ growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols: ...

PUBLIC HEALTH SIGNIFICANCE: By definition, a Depuration Processor (DP) "receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process." All areas submitted to the depuration plant for processing should be included for Process Verification, not just restricted areas as stated in the current section.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-206 to an appropriate committee as determined by the Committee Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-207

SPECIFIC REFERENCE: Model Ordinance Reference**:** XV.03 L.(2) Conditional Protocol Verification.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter XV.03L.(2).

(2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:

(a) The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;

(b) Environmental parameters including process water temperature, salinity, dissolved oxygen, and turbidity and/or other operational conditions may be inhibit the physiological process and must be identified. The conditions(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan shall be revised accordingly

(c) Shellstock which are processed during this conditional protocol

must meet the following release criteria before they may be released to market:

(i) Geometric mean (from three samples) of soft clams not to exceed 110 and no single sample to exceed 170; or

(ii) Geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 and no single sample to exceed 100.

(d) If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing whereupon the shellfish can be resampled for release criteria or the disposition of the shellfish shall be as follows:

(i) The Authority, in consultation with the depuration processor, may order the destruction of the shellfish; or

(ii) The Authority, in consultation with the depuration processor, may allow non-food use of the shellfish; or

(iii) The Authority, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapter V.

(e) When in Conditional Protocol Verification due to a failure of an established harvest area to meet the above Indices for Depuration Plant Performance, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive end product samples for each species depurated and for each harvest area used.

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in .03L(1).

(iii) If either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until the above Indices of Depuration Plant Performance are attained.

(f) When in Conditional Protocol Verification due to the use of a new harvest area as the source of shellfish or if a new depuration process has generated less than 10 process batches of data, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in XV.03L.(1).

(iii) If less than 10 process batches of data have been collected or either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, from this particular harvest area, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until 10 batches of data have been collected and the above Indices of Depuration Plant Performance are attained.

(3) When depuration units with multiple tanks are used, it is necessary to determine...

PUBLIC HEALTH SIGNIFICANCE: Guidance was not provided on how to fully utilize the triplicate end product assay data collected during Conditional Protocol Verification in the revised Chapter XV adopted in 1999. This provides clarification that when in Conditional Protocol Verification due to the utilization of a new harvest area or a new depuration plant, triplicate end product results will be recorded using the geometric mean value on a harvest lot basis. When a previously established area is in Conditional Protocol Verification, since a history of the area is known, the triplicate end product assay data are to be individually incorporated into the 10 consecutive lot database maintained for that particular growing area.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-207 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-208

SPECIFIC REFERENCE: Model Ordinance Reference: To be incorporated in the appropriate Model Ordinance Chapter.

TEXT OF ISSUE:

REQUESTED ACTION: Incorporate post-harvesting processing validation into appropriate Model Ordinance Chapter.

FDA allows the use of process safety labeling claims when proscribed conditions are met to reduce either all pathogens or specific pathogens to "non-detectable levels" as determined by specific laboratory analytical methodologies. FDA or the ISSC should develop a "Process System Design Validation Protocol" which can be used by State Shellfish Control Authorities in reviewing processor supplied studies or data to demonstrate the efficacy of any particular Post Harvest Treatment Process employed to meet the "process safety label claims." The Process System Design Validation Protocol should be modeled to the extent possible, to be consistent with other Food Process System Design Validation Protocols routinely employed by food control authorities. At a minimum the processor supplied validation process should include a Description of the Process, Inoculated Pack Studies, Storage and Shipping Temperatures Studies, and Statistical Evaluations.

The Inoculated Pack Studies for raw oysters are done to determine if the Post Harvest Treatment Process effectively reduces pathogenic strains of *Vibrio parahaemolyticus* and all strains of *V. vulnificus* to non-detectable levels as stipulated by regulatory label claims requirements. In such inoculated pack studies, consideration should be given to the following:

1. The types and strains of the vibrios to be used in an inoculation cocktail
2. The number of specific organisms to be incorporated in the cocktail and the method for enumeration.
3. The method for inoculating the oysters (i.e., injection or natural uptake).
4. Determination of probable study confounding variables such as initial temperature of the test oyster salinity, pH, and moisture content.
5. Sample size, sample times, number of samples to test, duplication and replication considerations, etc.
6. Calibration and verification procedures for relevant equipment employed in the post harvest treatment process.
7. Subjecting the inoculated pack to the post harvest treatment process for efficacy determination.
8. Conduct of storage studies of post harvest treated products (refrigerated and temperature abuse conditions)
9. Perform qualitative and quantitative laboratory analyses to determine Vibrio recovery from inoculated packs of initially processed and stored oysters.
10. 10. Perform appropriate statistical analyses, including stochastic modeling to determine process system efficacy and subsequent storage risk evaluations.

Validation, in the context of this issue, is defined as the process of ensuring that a defined set of control measures is capable of achieving appropriate control over a specific hazard(s) in a specific food(s).

Validation of a defined set of control measures requires that their effectiveness be measured against an expected outcome, normally expressed in terms of a performance criterion (e.g., heat treatment designed to reduce the level of *Salmonella* by 99.999% [5-log reduction] in a product). Thus, control measures should be validated to prove that they meet established performance criteria for controlling a specific hazard(s) in food(s).

A performance criterion is always associated with the application of one or more control measures. The process of validation will ensure that the selected set of control measures is effective in reaching the performance criterion and the underlying FSO, and thus in ensuring that the ALOP is achieved.

Prior to validation, the basis of a food safety system used to control a particular hazard(s) in a particular product(s) must be clearly known. This requires the following to be done.

1. Identification of the specific hazard(s) to be controlled, including microbial, chemical, and physical hazards.
2. Identification/establishment of a performance criterion for the process, i.e., the expected level of control of the hazard.

Identification of the food hygiene control measures to be used for control of the food hazard. It is important to carefully assess the nature of the processing system to determine what specific measures will be the controlling ones. Where thermal processing is the primary means of controlling the hazard, the actual controlling measures may be few. Where hurdle technologies are employed as the sole means of control, there may be multiple control measures.

Factors to consider in validation include: 1) consistency of demonstrating repeated efficacy of specified control measures, 2) determining that process variability are within acceptable levels, 3) determining the extent of the established science and process parameters necessary for laboratory validation of control measures, 4) adequacy of control measures requiring more than laboratory validation, 5) resource constraints, and 6) uncertainties associated with the validation of control measures.

Validation of food hygiene control measures is different from verification and routine monitoring. Validation is typically conducted prior to the initiation of a new food safety system to assure that it is capable of achieving the desired food safety outcome. Validation is repeated only infrequently when changes are made to the food safety system are significant enough to require revalidation. Alternatively it could be required if there is a change in the level of the hazard (e.g., microbial adaptation) or there is the emergence of a previously unidentified hazard or concern related to a particular food (e.g., Enterohaemorraghic *E. coli* in apple juice). In these situations, there is a need to reaffirm that the defined set of control measures are effective in controlling the hazard to the required level. Validation is not a process of monitoring the on-going assurance that a critical control point is operating properly within specifications for the control of a hazard in a food product. Additionally, it is not the ongoing process of verifying whether a HACCP plan is operating correctly.

For a more thorough understanding of the validation process, it is recommended that the Codex Alimentarius Commission's Committee on Food Hygiene discussion paper prepared by the United States of America with the assistance of Australia, Canada, France, and the International Dairy Federation entitled "Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures" (CX/FH 01/X, 2001) should be consulted. A further reference would be the document prepared for inoculated packed studies for vacuum or modified atmosphere packaging for refrigerated raw fishery products adopted by the National Advisory Committee on Microbiological Criteria for Foods on March 20, 1992.

PUBLIC HEALTH SIGNIFICANCE: Under certain conditions, *Vibrio vulnificus* and *Vibrio parahaemolyticus* can represent a significant public health risk to consumers of molluscan shellfish. Post harvest treatments (PHT) for oysters are emerging that reduce the pathogens of concern to non-detectable levels, and products subjected to such PHTs are allowed to make certain food safety labeling claims. From a public health perspective, it is imperative that process system designs of the individual PHTs be validated as to their efficacy in terms of "process" and subsequent storage considerations.

COST INFORMATION (IF AVAILABLE): Unknown.

ACTION BY 2001 VIBRIO VULNIFICUS SUBCOMMITEE: Recommended adoption of the subcommittee recommendation as amended**.**

Recommended adoption of Issue 01-208 as Interim Guidance and that the Issue be further referred to an appropriate committee for consideration as satisfactory compliance and for consideration of other pathogenic organisms. Further direction for this committee should be to develop specific satisfactory compliance language for the framework specified in the Interim Guidance.

Vibrio vulnificus Subcommittee recommendations on Issue 01-208 – "Post Harvest Processing Validation."

(a) The committee amended the issue to provide for a definition of "verification," so that a distinction could be made between the terms "Validation" and "Verification". The proposed definition for "Verification", in the context of this issue is as follows: "Verification" is the necessary monitoring activities of a validated process to ensure that no deviations are occurring within the process that would render the process to be incapable of obtaining the required validated performance standard. This definition of "verification" is to be inserted after the last sentence on page 110 of the issue.

(b) The phrase "Food Safety Objectives" is to be inserted immediately before the acronym FSO, in the third paragraph, page 110, and further, the acronym FSO is to become a parenthetical phrase.

(c) The phrase "Acceptable Level of Protection" is to be inserted fore the acronym "ALOP" and further, "ALOP" is to become a parenthetical phrase or term.

(d) The subcommittee thanked the Validation Working Group for its efforts and believe that it has provided a good general framework for conducting and reviewing invalidation studies for marine pathogenic vibrios.

(e) The subcommittee recommended to the Vibrio Management Committee that continued work needs to be conducted on this issue to augment the general considerations for process validation to be converted into more specific requirements for marine pathogenic vibrios.

Recommended changes to Issue 01-208 (New Interim Guidance):

FDA allows the use of process safety labeling claims when proscribed conditions are met to reduce either all pathogens or specific pathogens to "non-detectable levels" as determined by specific laboratory analytical methodologies. FDA or the ISSC should develop a "Process System Design Validation Protocol" which can be used by State Shellfish Control Authorities in reviewing processor supplied studies or data to demonstrate the efficacy of any particular Post Harvest Treatment Process employed to meet the "process safety label claims." The Process System Design Validation Protocol should be modeled to the extent possible, to be consistent with other Food Process System Design Validation Protocols routinely employed by food control authorities. At a minimum the processor supplied validation process should include a Description of the Process, Inoculated Pack Studies, Storage and Shipping Temperatures Studies, and Statistical Evaluations.

The Inoculated Pack Studies for raw oysters are done to determine if the Post Harvest Treatment Process effectively reduces pathogenic strains of *Vibrio parahaemolyticus* and all strains of *V. vulnificus* to non-detectable levels as stipulated by regulatory label claims requirements. In such inoculated pack studies, consideration should be given to the following:

1. The types and strains of the vibrios to be used in an inoculation cocktail
2. The number of specific organisms to be incorporated in the cocktail and the method for enumeration.
3. The method for inoculating the oysters (i.e., injection or natural uptake).
4. Determination of probable study confounding variables such as initial temperature of the test oyster salinity, pH, and moisture content.
5. Sample size, sample times, number of samples to test, duplication and replication considerations, etc.
6. Calibration and verification procedures for relevant equipment employed in the post harvest treatment process.
7. Subjecting the inoculated pack to the post harvest treatment process for efficacy determination.
8. Conduct of storage studies of post harvest treated products (refrigerated and temperature abuse conditions)
9. Perform qualitative and quantitative laboratory analyses to determine Vibrio recovery from inoculated packs of initially processed and stored oysters.
10. Perform appropriate statistical analyses, including stochastic modeling to determine process system efficacy and subsequent storage risk evaluations.

Validation, in the context of this issue, is defined as the process of ensuring that a defined set of control measures is capable of achieving appropriate control over a specific hazard(s) in a specific food(s).

Verification is the necessary monitoring activities of a validated process to ensure that no deviations are occurring within the process that would render the process to be incapable of obtaining the required validated performance standard.

Validation of a defined set of control measures requires that their effectiveness be measured against an expected outcome, normally expressed in terms of a performance criterion (e.g., heat treatment designed to reduce the level of *Salmonella* by 99.999% [5-log reduction] in a product). Thus, control measures should be validated to prove that they meet established performance criteria for controlling a specific hazard(s) in food(s).

A performance criterion is always associated with the application of one or more control measures. The process of validation will ensure that the selected set of control measures are effective in reaching the performance criterion and the underlying **Food Safety Objective (**FSO**)**, and thus in ensuring that the **Acceptable Level of Protection (**ALOP**)** is achieved.

Prior to validation, the basis of a food safety system used to control a particular hazard(s) in a particular product(s) must be clearly known. This requires the following to be done.

1. Identification of the specific hazard(s) to be controlled, including microbial, chemical, and physical hazards.
2. Identification/establishment of a performance criterion for the process, i.e., the expected level of control of the hazard.
3. Identification of the food hygiene control measures to be used for control of the food hazard. It is important to carefully assess the nature of the processing system to determine what specific measures will be the controlling ones. Where thermal processing is the primary means of controlling the hazard, the actual controlling measures may be few. Where hurdle technologies are employed as the sole means of control, there may be multiple control measures.

Factors to consider in validation include: 1) consistency of demonstrating repeated efficacy of specified control measures, 2) determining that process variability are within acceptable levels, 3) determining the extent of the established science and process parameters necessary for laboratory validation of control measures, 4) adequacy of control measures requiring more than laboratory validation, 5) resource constraints, and 6) uncertainties associated with the validation of control measures.

Validation of food hygiene control measures is different from verification and routine monitoring. Validation is typically conducted prior to the initiation of a new food safety system to assure that it is capable of achieving the desired food safety outcome. Validation is repeated only infrequently when changes are made to the food safety system are significant enough to require revalidation. Alternatively it could be required if there is a change in the level of the hazard (e.g., microbial adaptation) or there is the emergence of a previously unidentified hazard or concern related to a particular food (e.g., Enterohaemorraghic *E. coli* in apple juice). In these situations, there is a need to reaffirm that the defined set of control measures are effective in controlling the hazard to the required level. Validation is not a process of monitoring the on-going assurance that a critical control point is operating properly within specifications for the control of a hazard in a food product. Additionally, it is not the ongoing process of verifying whether a HACCP plan is operating correctly.

For a more thorough understanding of the validation process, it is recommended that the Codex Alimentarius Commission's Committee on Food Hygienediscussion paper prepared by the United States of America with the assistance of Australia, Canada, France, and the International Dairy Federation entitled "Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures" (CX/FH 01/X, 2001) should be consulted. A further reference would be the document prepared for innoculated packed studies for vacuum or modified atmosphere packaging for refrigerated raw fishery products adopted by the National Advisory Committee on Microbiological Criteria for Foods on March 20, 1992.

ACTION BY 2001 VIBRIO MANAGEMENT COMMITTEE: Recommended adoption of 01-208 as amended by the *Vibrio vulnificus* Subcommittee.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-208 as revised in the 2001*Vibrio vulnificus* subcommittee/(Vibrio Management Committee) report with the addition of "future" before "satisfactory"as indicated.

Recommended adoption of Issue 01-208 as Interim Guidance, and that the Issue be further referred to an appropriate committee for consideration as **future** satisfactory compliance and for consideration of other pathogenic organisms. Further direction for this committee should be to develop specific satisfactory compliance language for the framework specified in the Interim Guidance.

The remainder of the Subcommittee recommendation remains unchanged.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-209

SPECIFIC REFERENCE: Model Ordinance Reference: Chapter XI. @ 03 I (2).

TEXT OF ISSUE:

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XI. @.03 I (2).

(2) If a heat shock tank is used, the dealer shall completely drain and flush the tank at ~~three-hour intervals or less~~ the end of each day's operation so that all the mud and debris which have accumulated in the dip tank are eliminated.

PUBLIC HEALTH SIGNIFICANCE: North Carolina Shellfish Sanitation Section and North Carolina State University Seafood Laboratory jointly conducted 2 Heat Shock Tank studies to determine if there is any significant growth of bacteria in Heat Shock Tanks which are not completely drained and flushed at three hour intervals. These studies demonstrated conclusively that there is no significant growth in fecal coliform bacteria, thermophilic water plant count or standard plate count in Heat Shock Tanks which are not drained and flushed during the day's operation when compared to tanks which are drained and flushed at three hour intervals. See attached studies.

COST INFORMATION (IF AVAILABLE): No cost to industry or state agency.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-209 as amended.

(2) If a heat shock tank is used, **and the water is maintained at or above 140 degrees** the dealer shall completely drain and flush the tank at the end of each day's operation so that all the mud and debris which have accumulated in the dip tank are eliminated. **If the temperatures are maintained below 140 degrees, the dealer shall completely drain and flush the tank at three hour intervals**.

Recommended effective date of September 1, 2001 and expedited FDA review.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-210

SPECIFIC REFERENCE: Model Ordinance Reference: Chapter X .03.

TEXT OF ISSUE:

REQUESTED ACTION: Modify X.03 Other Model Ordinance Requirements to read:

Each dealer and importer shall comply with requirements specified in Chapter XI.03, Chapter XII.03, ChapterXIII.03, and ChapterXIV.03 AND any other chapters and sections of this Model Ordinance that may apply that are appropriate to the plant and the food being processed. However, monitoring and records IF required for these conditions and practices shall be made available to the FDA and to the appropriate State shellfish

standardization inspector and State shellfish standardization officer upon request within a reasonable time as to determine the status of shellstock to be processed, unless specifically stated.

PUBLIC HEALTH SIGNIFICANCE: The Authority will have access to all records to determine compliance with the Model Ordinance in a reasonable time if the shellstock is acceptable.

COST INFORMATION (IF AVAILABLE): Not available at this time.

ACTION BY 2001 TASK FORCE II: Referred to 2001 Task Force III.

ACTION BY 2001 GENERAL ASSEMBLY: See Task Force III, page 141.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-211

SPECIFIC REFERENCE: Model Ordinance Reference: XII.01B.

TEXT OF ISSUE:

REQUESTED ACTION: Modify XII.01B to read:

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shellfish ~~are:~~ do not exceed an internal temperature of 45° Fahrenheit (7.2° Centigrade) for more than 2 hours.

~~(1) Maintained at an internal temperature of 45° Fahrenheit (7.2° Centigrade) or less; and [C]~~
~~(2) Maintained at a temperature less than 45° Fahrenheit (7.2° Centigrade) in any portion of frozen shellfish thawed for repacking. [C]~~

PUBLIC HEALTH SIGNIFICANCE: This issue was originally submitted as part of Issue 99-209, and is being submitted separately so that it can be considered on its own merits, and not be subject to the controversy currently surrounding other concepts within Issue 99-209.

Allowing repacked shucked shellfish to exceed 45° F for 2 hours does not present a significant public heath hazard. The industry standard is to keep shucked product iced, which means that any human pathogenic bacteria in the shellfish will have been forced into a resting mode at best. Most bacteria, and certainly all the vibrios, will not significantly recover from their lag phase of growth within the 2 hours proposed above for repacking. Furthermore, the repacked shellfish will generally be immediately iced.

There are a significant number of repackers that purchase-shucked product that has not yet been blown. These repackers must use a significant amount of flowing water in the blower tanks to be able to clarify the shellfish. One cannot realistically add enough ice to keep this flowing water at or below 45° F. The current requirements above are prime examples of good intentions that have gone too far.

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-211 as amended.

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked **shucked** shellfish do not exceed an internal temperature of 45° Fahrenheit (7.2° Centigrade) for more than 2 hours.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-212

SPECIFIC REFERENCE: Model Ordinance Reference: 1999 Model Ordinance Definitions.

TEXT OF ISSUE:

NOTE: The following changes are necessary to make these sections of the Model Ordinance consistent with Chapter X.04.B.2.

REQUESTED ACTION: Modify 1999 Model Ordinance Definition of Repacker:

B. Definition of Terms.

(82) Repacker (RP) means a ~~any~~ dealer ~~person, other than the original certified shucker packer~~, who buys, repacks and sells ~~repackages shucked~~ shellfish ~~into other containers~~. They are not authorized to shuck shellfish.

PUBLIC HEALTH SIGNIFICANCE: Several sections of the Model Ordinances concerning Repacking of shellfish are inconsistent with Chapter X.04.B.2. The purpose of this issue is to bring conformity to all areas of the Model Ordinance concerning Repacking of Shellfish. Currently, the critical limits for repackers handling shellstock are omitted from the Model Ordinance. This issue also adds the controls utilized in the rest of the Model Ordinance for receiving, storage and handling of shellstock.

COST INFORMATION (IF AVAILABLE): Not provided.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-212 to appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-213

SPECIFIC REFERENCE: Model Ordinance Reference: 1999 Model Ordinance: Chapter XII.

TEXT OF ISSUE:

NOTE: The following changes are necessary to make these sections of the Model Ordinance consistent with Chapter X.04.B.2.

Requested Action: Modify 1999 Model ordinance Chapter XII Title.

XII. REPACKING OF ~~SHUCKED~~ SHELLFISH

PUBLIC HEALTH SIGNIFICANCE: Several sections of the Model Ordinances concerning Repacking of shellfish are inconsistent with Chapter X.04.B.2. The purpose of this issue is to bring conformity to all areas of the Model Ordinance concerning Repacking of Shellfish. Currently, the critical limits for repackers handling shellstock are omitted from the Model Ordinance. This issue also adds the controls utilized in the rest of the Model Ordinance for receiving, storage and handling of shellstock.

COST INFORMATION (IF AVAILABLE): Not provided.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-213 to appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

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ISSUE NUMBER: 01-214

SPECIFIC REFERENCE: Model Ordinance Reference: 1999 Model Ordinance Chapter XII.01.A.

TEXT OF ISSUE:

NOTE: The following changes are necessary to make these sections of the Model Ordinance consistent with Chapter X.04.B.2.

Requested Action: Modify 1999 Model Ordinance Chapter XII.01.A.

XII. REPACKING OF SHUCKED SHELLFISH

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack ~~only~~ shellfish or shellstock which is:

(1) Originated from a ~~dealer~~ licensed harvester who has: ~~; and~~ [C]

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or

(2) Obtained from a certified dealer who has:

(a) Identified the shellstock with a tag on each container or transaction record with each bulk shipment; and

(b) ~~(2) Are~~ Identified the shellfish with a label as outlined in Chapter X.06. [C]

PUBLIC HEALTH SIGNIFICANCE: Several sections of the Model Ordinances concerning Repacking of shellfish are inconsistent with Chapter X.04.B.2. The purpose of this issue is to bring conformity to all areas of the Model Ordinance concerning Repacking of Shellfish. Currently, the critical limits for repackers handling shellstock are omitted from the Model Ordinance. This issue also adds the controls utilized in the rest of the Model Ordinance for receiving, storage and handling of shellstock.

COST INFORMATION (IF AVAILABLE): Not provided

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-214 to appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-215

SPECIFIC REFERENCE: Model Ordinance Reference: 1999 Model Ordinance Chapter XII.01.

TEXT OF ISSUE:

NOTE: The following changes are necessary to make these sections of the Model Ordinance consistent with Chapter X.04.B.2.

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XII.01.

B. Shellstock ~~Process~~ Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and

(2) Once placed under temperature control and until sale to the final processor or final consumer, shellstock shall be;

(a) Iced; or

(b) Placed and stored in a storage area or conveyance maintained at 45? Fahrenheit (7.2? Centigrade) or less; and

(c) Not permitted to remain without ice, mechanical refrigeration or other approved means of refrigeration, as required in §B(1) or §B(2) for more than 2 hours at points of transfer such as loading docks.

(3) ~~(1)~~ Maintained at an internal temperature of 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less; and [C]

(4) ~~(2)~~ Maintained at a temperature less than 45 ^{o} Fahrenheit 7.2 ^{o} Centigrade) in any portion of frozen shellfish thawed for repacking. [C]

PUBLIC HEALTH SIGNIFICANCE: Several sections of the Model Ordinances concerning Repacking of shellfish are inconsistent with Chapter X.04.B.2. The purpose of this issue is to bring conformity to all areas of the Model Ordinance concerning Repacking of Shellfish. Currently, the critical limits for repackers handling shellstock are omitted from the Model Ordinance. This issue also adds the controls utilized in the rest of the Model Ordinance for receiving, storage and handling of shellstock.

COST INFORMATION (IF AVAILABLE): Not provided.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-215 to appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

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ISSUE NUMBER: 01-216

SPECIFIC REFERENCE: Model Ordinance Reference: 1999 Model Ordinance Chapter XII.02.C.

TEXT OF ISSUE:

NOTE: The following changes are necessary to make these sections of the Model Ordinance consistent with Chapter X.04.B.2.

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XII.02.C.

C. Prevention ~~of Cross~~ from Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.

(b) Shellstock shall not be placed in container with standing water for the purpose of

washing shellstock or loosening sediment

(c)~~(a)~~ Shucked shellfish shall be protected from contamination. [$S^{C/K}$]

(d)~~(b)~~ Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [$S^{K/0}$]

PUBLIC HEALTH SIGNIFICANCE: Several sections of the Model Ordinances concerning Repacking of shellfish are inconsistent with Chapter X.04.B.2. The purpose of this issue is to bring conformity to all areas of the Model Ordinance concerning Repacking of Shellfish. Currently, the critical limits for repackers handling shellstock are omitted from the Model Ordinance. This issue also adds the controls utilized in the rest of the Model Ordinance for receiving, storage and handling of shellstock.

COST INFORMATION (IF AVAILABLE): Not provided.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-216 to appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

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ISSUE NUMBER: 01-217

SPECIFIC REFERENCE: Model Ordinance Reference: 1999 Model Ordinance Chapter XII.03.H.

TEXT OF ISSUE:

NOTE: The following changes are necessary to make these sections of the Model Ordinance consistent with Chapter X.04.B.2.

REQUESTED ACTION: Modify 1999 Model Ordinance Chapter XII.03.H.

H. Shellstock Storage and Handling.

(1) The dealer shall:

(a) Assure the shellstock is:

(i) Alive;

(ii) Reasonably free of sediment; and

(iii) Culled;

(b)~~(a)~~ Not commingle shellfish from different lots; [K]……

* Renumber rest of section

PUBLIC HEALTH SIGNIFICANCE: Several sections of the Model Ordinances concerning Repacking of shellfish are inconsistent with Chapter X.04.B.2. The purpose of this issue is to bring conformity to all areas of the Model Ordinance concerning Repacking of Shellfish. Currently, the critical limits for repackers handling shellstock are omitted from the Model Ordinance. This issue also adds the controls utilized in the rest of the Model Ordinance for receiving, storage and handling of shellstock.

COST INFORMATION (IF AVAILABLE): Not provided.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-217 to appropriate committee as determined by the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-218

SPECIFIC REFERENCE: Model Ordinance Reference**:** XV.03.B.(1)(b).

TEXT OF ISSUE:

REQUESTED ACTION: Delete language in XV.B.(1)(b) and replace with new language:

B. Plumbing and Related Facilities.

(1) Handwashing facilities shall be provided which are:

(a) Convenient to work areas;

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; ~~if applicable, separate three compartment sinks;~~ and

(c) Directly plumbed to an approved sewage disposal system.

PUBLIC HEALTH SIGNIFICANCE: Item should be deleted for consistency in Model ordinance language. The new language suggested section change is consistent with the language in Chapters XI.03B (1)(b); XII.03B (1)(b) and XIII.03B (1)(b).

COST INFORMATION (IF AVAILABLE): None.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-218 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

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ISSUE NUMBER: 01-219

SPECIFIC REFERENCE: Model Ordinance Reference**:** Chapter XV.01; Chapter XV.02; Chapter XV.03.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter XV sections .01 - Critical Control Points, .02 - Sanitation, and .03 - Other Model Ordinance Requirements, by adding deficiencies codes for consistency with Chapters XI, XII, XIII and XIV. See attached document for modifications. **[Note: C – Critical; K– Key; S– Swing]**

.01 - Critical Control Points.

A. Receiving Critical Control Point – Critical Limits. The dealer shall receive and depurate only shellstock which is:

(1) Obtained from a licensed harvester who has:

(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and

(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and

(2) Originates from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment; [C] and

(3) Obtained from a special licensed harvester who has:

(a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; [C] and

(b) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. [C]

B. Processing Critical Control Points – Critical Limits. The dealer shall assure that:

(1) All depuration lots are treated for a minimum of 44 hours; [C] and

(2) The water treatment system is operating to design specifications; [C] and

(3) All critical limits established during verification of the specific depuration process are being met. [C]

C. Finished Shellstock Storage Critical Control Point – Critical Limits. The dealer shall assure that:

(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X. 08; [C] and

(2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:

(a) Iced; [C] or

(b) Placed in a storage area or conveyance maintained at 45° Fahrenheit (7.2° Centigrade) or less; [C] and

(c) Not permitted to remain outside temperature control for more than 2 hours at points of transfer such as loading docks. [C]

.02 – Sanitation

A. Safety of Water for Processing and Ice Production

(1) Water Supply**.**

(a) Dealers shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]

(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]

(i) Prior to use of the water supply; [C]

(ii) Every six months while the water supply is in use; [K] and

(iii) After any water supply has been repaired and disinfected. [S C/K]

(2) Ice production**.** Any ice used in the processing or storage of shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; [C] or

(b) Come from a facility approved by the Authority or the appropriate regulatory agency. [C]

(3) Shellstock washing

(a) Water from either a potable water supply, or a growing area in the approved classification, or the restricted area at the time and place of harvest, shall be used to wash shellstock. [C]

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority; [K]

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing, which, after disinfection, meets the coliform standards for drinking water; and does not leave any unacceptable residues in the shellstock; [C]

(iii) Test wash water daily for bacteriological water quality; [S C/K]

(iv) Clean, service, and test disinfection units at the frequency necessary to ensure effective disinfection. [K]

(c) The dealer may use ultra-violet (UV) disinfection in his recirculating wash water system, provided that the turbidity of the water to be disinfected:

(i) shall not exceed 20 nephelometric turbidity units (NTUs); [K] and

(ii) Is measured using the method in the APHA Standard Methods for the Examination of Water and Wastewater. [K]

(d) Food contact plumbing which is designed and installed to permit effective cleaning and sanitization shall be used. [C]

(4) Depuration Process Water**.**

The dealer shall:

(a) Continuously treat process water with a disinfection system approved by the Authority that does not leave any unacceptable residue in the shellstock; [C] and

(b) Verify that the disinfection system produces process seawater with no detectable

coliform organisms as measured using an NSSP approved method in the tank influent according to the following sampling protocols.

(i) If the source water is an approved growing area, approved well, or other approved source, then the tank influent produced by each disinfection unit is evaluated once per process batch; [C]

(ii) If the source water is a restricted growing area, then:

(a) A study meeting the requirements of Chapter X. 08C.(2)(b) is required; [C]

(b) The tank influent produced by each disinfection unit is evaluated daily; [C] and

(c) Source water prior to final disinfection must meet the water quality criteria for restricted for depuration in accordance with Chapter IV. 02G-H. [C]

(iii) If the source water is a recirculating water system, then:

(a) A study meeting the requirements of Chapter X. 08C.(2)(b) is required; [C] and

(b) The tank influent produced by each disinfection unit is verified daily. [C]

(c) A prohibited growing area may not be used for source water. [C]

(5) Plumbing and Related Facilities**.**

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies; [C] and

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]

(b) Shellstock storage tanks and related plumbing shall be fabricated from safe materials, and tank construction shall be such that it :

(i) is easily accessible for cleaning and inspection [K] ;

(ii) is self-draining; [K] and

(iii) meets the requirements for food contact surfaces. [K]

(b) Depuration Plant Design and Construction.

The dealer shall ensure that:

(i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; [K]

(ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly circulated throughout all the shellfish containers within a given tank; [K]

(iii) Shellfish containers allows process water to flow freely and uniformly to all shellfish within each container. [K]

(6) Depuration unit

(a) Depuration unit including depuration tanks, all reservoir tanks, and related piping shall be fabricated from safe materials, and depuration unit construction is such that it:

(i) is easily accessible for cleaning and inspection; [K]

(ii) is self-draining; [K] and

(iii) meets the requirements for food contact surfaces. [K]

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to Shellfish Industry Equipment Construction Guides (August 1993), U. S. Department of Health and Human Services. [K]

(b) The dealer shall use only equipment and utensils, including approved plasticware which are:

(i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; [K] and

(iii) fabricated from food grade materials. [K]

(c) The dealer shall assure that all joints on food contact surfaces:

(i) have smooth easily cleanable surfaces; [K] and

(ii) are welded. [K]

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in §.02 B (1) (a), (b), and (c). [K]

(2) Cleaning and sanitizing of food contact surfaces**.**

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses. [K]

(ii) Wash, rinse and sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]

(b) All conveyances and equipment which come into contact with stored shellstock in such a manner and such a frequency shall be cleaned and maintained as necessary to prevent shellstock contamination. [O]

(c) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]

(d) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. [K]

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S C/K]

(b) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment; [K]

(2) Employee practices**.**

(a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:

(i) Before starting work; [K]

(ii) After each absence from the work station;[K]

(iii) After each work interruption; [K] and

(iv) any time when their hands may have become soiled or contaminated. [K]

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities

(1) Handwashing facilities with warm water at a minimum temperature of 110° Fahrenheit (43° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided; [S K/O]

(2) Sewage [C] and liquid disposable wastes [K] shall be properly removed from the facility.

(3) An adequate number of conveniently located toilets shall be provided. [K]

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper [K] in a suitable holder [S K/O].

E. Protection from Adulterants.

(1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing; [K]

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]

(3) Conveyances or devices used to transport shellstock shall be constructed, maintained and operated to prevent contamination of the shellstock. If overhead monorails or conveyors are used, the dealer shall take precautions to assure that hydraulic fluids or lubricants do not leak or drip onto the shellstock or conveyance surfaces. [K]

(4) Adequate ventilation shall be provided to minimize condensation in areas where shellfish are stored, processed or packed. [S K/C]

(5) Shellstock packing activities shall be conducted to provide adequate protection from contamination and adulteration. [K]

(6) Protection of ice used in shellstock shipping.

(a) Any ice which is not made on-site in the depuration facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S C/K]

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S C/K]

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; [K]

(ii) Detergents, sanitizers, and related cleaning agents; [K] and

(iii) Caustic acids, polishes, and other chemicals. [K]

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]

(2) Use and labeling of toxic compounds**.**

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]

(b) Cleaning compounds and sanitizing agents shall be used only in accordance with applicable federal and state laws and regulations. [K]

(c) Detergents, sanitizers, and other cleaning supplies shall be used only in strict accordance with the manufacturer's label instructions. [K]

(d) Toxic substances shall be used only in strict accordance with the manufacturer's label instructions. [K]

~~(e) The dealer shall not store toxic substances above shellfish or food contact surfaces.~~ *[Editorial deletion – Item is repeated in Section .02F(1)(c)]*

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the Federal Register. [K]

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. [K]

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from his facility and his activities. [K]

.03 - Other Model Ordinance Requirements

A. Plants and Grounds.

(1) General

(a) The physical facilities shall be maintained in good repair. [O]

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials are cleaned or stored. [K]

(2) Flooding. Facilities in which shellstock are stored, packed, or repacked shall be located so that these facilities are not subject to flooding during ordinary high tides. If facilities are flooded: [C]

(a) Shellstock processing or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]

(b) Any shellstock coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use.[C]

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S C/K]

(4) Separation of operations. Manufacturing activities which could result in the contamination of the shellstock shall be separated by adequate barriers. [K]

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. [O]

(b) Interior surfaces are kept in good repair. [O]

(c) All dry area floors are hard, smooth, easily cleanable and in good repair; [O] and

(d) All wet area floors used in areas to store shellstock, food processing, and cleaning equipment are constructed of easily cleanable, impervious, and corrosion resistant materials which:

(j) Are graded to provide adequate drainage; [O]

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O]

(iii) Have sealed junctions between floors and walls to render them impervious to water; [O] and

~~(iv) Are maintained in good repair.)~~ [See Issue 01-202]

(6) Walls and Ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials shall be constructed of easily cleanable, corrosion resistant, impervious and light colored materials. [O]

(7) Grounds.

(a) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(i) Rodent attraction and harborage; [O]

~~(ii) Excessively dusty yards, roads or parking lots; and~~ [Editorial deletion – for consistency in MO Language. Statement does not appear in Chapters XI, XII, and XIII]

(iii) Inadequate drainage. [O]

~~(b) The dealer shall operate his facility to assure that dirt and other filth which may be a source of shellfish contamination are excluded from his facility and his activities.~~ *[Editorial deletion – Item is repeated in Section .03A(3)]*

B. Plumbing and Related Facilities.

(1) Handwashing facilities shall be provided which are:

(a) Convenient to work areas; [O]

~~(b) If applicable, separate three compartment sinks; [O] and~~ [See Issue 01-218]

(c) Directly plumbed to an approved sewage disposal system. [S O/K]

(2) The dealer shall provide at each handwashing facility:

(a) A supply of hand cleansing soap or detergent; [K]

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]

(c) An easily cleanable waste receptacle; [O] and

(d) Handwashing signs in a language understood by the employees; [O]

(3) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; [K] and

(b) Handwashing facilities adequate in number and size for the number of employees, and are located where supervisors can observe employee use. [K] (4) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

(a) Used in shellstock storage; [K]

(b) Used for food holding units (e. g. refrigeration units); [K]

(c) Cleaned by hosing, flooding, or similar methods; [K] and

(d) Subject to the discharge of water or other liquid waste, including, if applicable, three compartment sinks, on the floor during normal activities; [K]

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S C/K]

(6) Installation of drainage or waste pipes over processing or storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted [K]

C. Utilities.

Ventilation, heating, or cooling systems shall not create conditions that may cause the shellstock to become contaminated. [S C/K]

D. Insect and Vermin Control.

The dealer shall employ necessary internal and external insect and vermin control measures to assure that insects and vermin are not present in the facility, including:

(1) Tight fitting, self-closing doors; [K]

(2) Screening of not less that 15 mesh per inch; [K] or

(3) Controlled air currents. [K]

E. Disposal of Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to:

(a) Minimize odors; [O]

(b) Prevent attraction, [O]

(c) Avoid the creation of nuisance conditions. [O]

F. Equipment Construction for Non-food Contact Surfaces.

(1) The dealer shall use only equipment which is constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock. [O]

(2) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks, to construct any non-food contact surfaces in shellfish storage or handling areas. [O]

G. Cleaning and Sanitizing of Non-food Contact Surfaces.

(1) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. [K]

(2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]

H. Shellstock Storage and Handling.

(1) The dealer shall assure that shellstock is:

(a) Reasonably free of sediment; [O] and

(b) Culled [K]

(2) Shellstock shall be stored in a protected location which assures complete and rapid drainage of water away from the shellstock by:

(a) Placing shellstock at an adequate height off the floor; [K] or

(b) Grading the floor. [O]

(3) Any mechanical refrigeration equipment used for shellstock storage shall be adequate in size and are equipped with:

(a) An automatic temperature regulating control; [K] and

(b) Installed thermometers to accurately measure temperature within the storage compartments. [K]

(4) Inspect incoming shipments and shall reject dead or inadequately protected shellstock. [K]

(5) Ensure that separate dry storage facilities are provided for depurated and undepurated shellfish; [K] and

(6) Cull and wash the shellstock prior to loading into the depuration tanks. This process may occur before the shellstock is received at the facility by;

(a) Licensed harvester(s) at the harvest site; [K] or

(b) Certified dealer(s) at their certified facility. [K]

(7) Assure that culled shellfish are destroyed or disposed of in such a manner as to prevent their use for human food. [K]

(8) Transport, store, and handle shellstock so that:

(a) Shellstock potential for normal physiological activity during depuration is not compromised; [K] and

(b) Shellstock quality is not degraded. [K]

(9) Assure that different harvest lots of shellfish are not commingled during washing, culling,

processing, or packing. If more than one harvest lot of shellfish are being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. [K]

(10) Wash and cull shellstock after depuration and pack the shellstock in clean shipping containers fabricated from safe materials; [K]

(11) Depurated packaged shellstock shall be protected from contamination at all times

and be held at an ambient temperature not to exceed 45° Fahrenheit (7.2° Centigrade). [K]

I. Personnel. Any employee handling shucked shellfish shall be required to:

(1) Wear effective hair restraints; [O]

(2) Remove any hand jewelry that cannot be sanitized or secured; [O]

(3) Wear finger cots or gloves if jewelry cannot be removed; [O]

(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. [O]

(5) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(a) Store clothing or other personal belongings; [O]

(b) Eat or drink; [K]

(c) Spit; [K] and

(d) Use tobacco in any form. [K]

J. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces. [K]

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; [K] and

(b) Knowledgeable of personal hygiene and sanitary practices. [K]

(4) The dealer shall require:

~~(a) Supervisors to assure employees follow proper hygiene practices.~~ (See Issue 01-203]

(b) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant equipment clean-up; [K]

(ii) Rapid product handling; [K] and

(iii) Shellstock protection from contamination.[K]

(c) Employees

(i) to be trained in proper food handling and personal hygiene practices, [K] and

(ii) to report any symptoms of illness to their supervisor. [K]

PUBLIC HEALTH SIGNIFICANCE: The purpose of this issue is to provide uniformity on the same level of deficiency codes that appear on Chapters XI, XII, XIII and XIV. Language used on Chapter XV sections .01-Critical Control Points, .02 - Sanitation, and .03 Other Model Ordinance Requirements is the same as the other chapters used for dealer certification. This will be in accordance with the NSSP inspection form and the FDA 3038 Dealer Certification Form requirements for Depuration Processor certification.

COST INFORMATION: None.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-219 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-220

SPECIFIC REFERENCE: Model Ordinance Reference: X .08 Wet Storage in Artificial Bodies of Water.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter X.08.C:

.08 Wet Storage in Artificial Bodies of Water.

C. Water Supply.
(1) …
(2) …
(3) …
(a) …
(b) …
(c) …
(d) When ultraviolet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for periodic servicing, new ultraviolet bulbs ~~are~~ shall be installed and old bulbs discarded ~~a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.~~

Implementation date: If passed by the 2001 ISSC, the effective date for implementation of this issue shall be immediately upon concurrence by the Food and Drug Administration.

PUBLIC HEALTH SIGNIFICANCE: The current requirement in the Model Ordinance to require reverification of system performance following replacement of ultraviolet bulbs is not logical, provides no added public health safety and it is an unnecessary burden and expense to place on dealers.

Performing a ultraviolet bulb change only serves to enhance the performance of the disinfection system not degrade it. Certainly with a system that uses a UV bulb inside of quartz sleeves, an operator is likely to clean the quartz sleeve if he has gone to the trouble to remove it to replace the bulb, which will further enhance the performance of the system.

The only public health risk might come from an operator installing old bulbs that still would illuminate but not emit sufficient ultraviolet light. The new language requiring only new bulbs be installed and old ones discarded should address this.

COST INFORMATION (IF AVAILABLE): Water samples in Washington State cost $26 each. Each reverification requires for samples be sent for a total of $104. This is a cost incurred by a dealer any time a bulb blows or he changes bulbs in servicing the UV unit (normally annually). Based on this, eliminating this requirement could represent a cost savings of several hundred dollars per year for the dealer and it would free up lab time at the state lab for testing that could be more important to protecting public health.

ACTION BY 2001 TASK FORCE II: Recommended adoption of Issue 01-220 as submitted.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Did not concur with Conference action. Recommended Issue 01-220 be returned to appropriate committee for further consideration. Provided comments. See Attachment at end of Task Force II.

ACTION BY ISSC EXECUTIVE BOARD: Recommended referral of Issue 01-220 to appropriate committee as determined by Conference Chairman.

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ISSUE NUMBER: 01-221

SPECIFIC REFERENCE: Model Ordinance Reference: X .08 Wet Storage in Artificial Bodies of Water.

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter X.08.C.

.08 Wet Storage in Artificial Bodies of Water.

C. Water Supply.

(1) General.

(a) …

(b) …

(c) …

(d) …

(e) …

(f) Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multitube MPN test per 100 ml. for potable water.

~~(g)~~ (i)When the laboratory analysis of a single sample of disinfected water entering the wet storage tanks shows any positive result for the coliform group, daily sampling shall be immediately instituted until the problem is identified and eliminated.

(ii) Upon notification from the certified lab processing wet storage water samples of any single sample exceeding 14 MPN (growing area standard), product in the wet storage system at that time shall be placed on hold and not released for sale until the problem causing the disinfected water to show a positive result for the fecal coliform group is eliminated and verified according to Chapter X §. 08.C. (1)(g).

(iii) In the event the wet storage system must be shut down to effect repairs and that period of time is sufficient to sacrifice the health of the animals, shellstock shall be discarded, placed in an approved relay meeting the requirement of Chapter V or returned to a growing area under agreement with the Authority to assure they will not be re-harvested for sale in less than 6 months. On completion of repairs the ability of the system to produce water free from bacteria in the coliform group shall be reaffirmed in accordance with Chapter X § .08 C.(3)(c).

~~(h)~~ (g) When the problem that is causing disinfected water to show a positive result for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the immediate collection, within a 24 hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.

~~(i)~~ (h) For water that is disinfected by ultraviolet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewate*r, APHA.

~~(j)~~ (i) The disinfection unit(s) for the water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

Implementation date: If passed by the 2001 ISSC, the effective date for implementation of this issue shall be immediately upon concurrence by the Food and Drug Administration.

PUBLIC HEALTH SIGNIFICANCE: On December 22, 2000 Washington State Department of Health issued a letter informing Taylor Shellfish Company that in the event any of the routine water samples from their recirculating wet storage systems came back positive for fecal coliform bacteria, that product in the system was to be placed on hold. Product was not to be released for sale until the problem causing the positive fecal test was identified, repaired and the repair validated through sampling as prescribed in the Model Ordinance (MO).

While the MO states "Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group...", it is silent on the disposition of the product in the system if a water sample detects any level of coliform bacteria.

Taylor Shellfish has two recirculating wet storage systems, both of which have been in service for several years. On rare occasions, the 23,000-gallon system at the Shelton, Washington processing plant has had samples with fecal coliform levels in the 2-8 range. While we concur that these samples could be indicative of a problem with the

water treatment system, we do not concur that this represents a public health hazard that merits putting all the product in the system on hold for what could be in excess of a week to get validation samples processed at the state certified lab. The lab does not operate on the weekend and will not receive samples late in the week for processing. If a failed sample notice were to come late in the week it would be well into the following week before validation samples could show the problem has been resolved.

This issue attempts to establish a response threshold for putting product on hold only if a sample is returned in excess of 14 MPN (the growing water standard).

COST INFORMATION (IF AVAILABLE): This particular system may have in the neighborhood of 30,000 pounds of product in it worth upwards of $70,000 dollars. This represents roughly 3 days inventory moving through the system. Were it to be precluded from sale, depending on available tides, it is unlikely there will be available inventory to substitute for several days. If this issue is not adopted, under current MO interpretation, a 2 MPN sample result could potentially lose the company several days of sales and tie up $70,000 worth of product that could be sold with no public health risk.

ACTION BY 2001 TASK FORCE II: Recommended referral of Issue 01-221 to appropriate committee as determined the Conference Chairman.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-222

SPECIFIC REFERENCE: Model Ordinance Reference: I.02F. Add paragraph (3**)**

TEXT OF ISSUE:

REQUESTED ACTION: Modify Chapter 1.02F:

F. Inspections.
(1) After any person is certified……
(2) The Authority shall provide ……
(3) To assure competent assistance when HACCP plans are to be reviewed/verified, the Authority shall notify the dealer, or a designated administrative principal at least three days prior to the audit visit.

PUBLIC HEALTH SIGNIFICANCE: To review/verify a HACCP plan usually requires several hours of an auditor's time. The investigations cannot be conducted without the assistance of a company supervisor possessing full knowledge of procedures, places and personnel involved in recording/maintaining data required by the plan. In the absence of key HACCP personnel, poorly qualified people are called upon, creating inefficiencies and excessive costs for both the auditor and the shellfish company.

COST INFORMATION (IF AVAILABLE): Not Provided.

ACTION BY 2001 TASK FORCE II: Recommended No Action. Rationale: States conduct unannounced inspections.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurs with Conference action.

* * *

ISSUE NUMBER: 01-223

SPECIFIC REFERENCE: Model Ordinance Reference**:** Definitions.

TEXT OF ISSUE:

(92) Shellfish means all species of:

(a) Oysters, clams or mussels, whether:

(i) Shucked or in the shell;

(ii) Fresh, or frozen; and

(iii) Whole or in part; and

(iv) Heat processed, except for low acid canned foods; and
Scallops in any form, except when the final product from is the adductor muscle only.

PUBLIC HEALTH SIGNIFICANCE: Literature and studies of food borne outbreaks involving molluscan shellfish indicate that the only etiology is the contamination of the growing waters. This identifies the source of the shellstock as the only true critical control point in any hazard analysis. Within the United States all shellfish, even that product that is going to low acid canned food trade, is harvested in compliance with the National Shellfish Sanitation Program (NSSP). Recent food borne outbreak(s) in New York, due to Norwalk like virus in clams, have brought to light that certain imported molluscan shellfish products fail to comply with the requirements of the NSSP. These products were labeled as "cooked" and therefore not required to meet the standards for raw shellfish set forth in the Model Ordinance. Investigation found that the implicated product was indeed raw and came from a country that is not a member of the ISSC. In order to meet the objective of the NSSP "to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria", all molluscan shellfish products that are not heat processed equivalent to the low acid canned foods must come from countries that agree to meet the standards of the NSSP. Changing the definition of "shellfish" will place cooked products under the NSSP and eliminate the shipment of misbranded, adulterated products.

COST INFORMATION (IF AVAILABLE): Not available.

ACTION BY 2001 TASK FORCE II: Recommended Referral of issue 01-123 to 2001 Task Force III

ACTION BY 2001 GENERAL ASSEMBLY: See Task Force III, page 142.

ACTION BY USFDA: Concurs with Conference action.

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ISSUE NUMBER: 01-224

SPECIFIC REFERENCE: Model Ordinance Reference: Chapter X, section .09.

TEXT OF ISSUE:

Move the contents of existing Chapter X, section .09 to a new Chapter XVI and rewrite as follows:

CHAPTER XVI

POST HARVEST PROCESSING

.01 Post-Harvest Processing.

(A) If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s)

are at safe levels for the at risk population in product that has been subjected to the process.

(a) For processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in product that has been subjected to the process shall be non-detectable (<3 MPN/gram), to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992.

(b) For processes that target *Vibrio parahaemolyticus*, the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<1 CFU/0.1 gram).

(c) For processes that target other pathogens, the level of those pathogens in product that has been subjected to the process shall be below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study approved by the Authority, with the concurrence of FDA.

(e) The HACCP plan shall include:

(i) Process controls to ensure that the end point criteria are met for every lot; and,

(ii) A sampling program to periodically verify that the end point criteria are met.

(2) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(3) Keep records in accordance with Chapter X.07.

(B) A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:

(1) "Processed for added safety," if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;

(2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(4) A term that describes the type of process applied (e.g. "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in (B)(1)-(3).

(C) For the purposes of refrigeration, if the end product is dead, the product shall be treated as shucked product. If the end product is live, the product shall be treated as shellstock.

Eliminate Chapter X, section .10, "Processed Products with Labeling Claims for Safety."

PUBLIC HEALTH SIGNIFICANCE: Protection of at-risk consumers and added incentives for post-harvest labeling.

COST ESTIMATE: None.

ACTION BY 2001 TASK FORCE II:

1. Recommended adoption of Issue 01-224 as submitted.
2. Recommended that an appropriate committee be established by the Conference Chairman with the following instructions: consider the establishment of a new PHT dealer classification and any other relevant topics.
3. Recommended an effective date of October 1, 2001 and request expedited FDA approval.
4. Recommended that FDA identify in the ICSSL those firms that have been identified by the SSCA as having an approved post harvest treatment process.

Note: Recommendation number four (4) on Issue 01-224 may be divided and debated separately.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendations 1-3 of 2001 Task Force II. Referred recommendation 4 to appropriate committee as determined by Conference Chairman.

ACTION BY USFDA: Concurs with Conference action. Provided comments. See Attachment at end of Task Force II.

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ISSUE NUMBER: 01-225

SPECIFIC REFERENCE: Model Ordinance Reference: Guidance Documents.

TEXT OF ISSUE:

Create a new section, B.6, in the Guidance Document Section IV, B. – Sanitation of Harvesting, Processing and Distribution of Shellfish.

B.6. – STATE INSPECTION PROGRAM EVALUATION CRITERIA

1. All dealers are required to be properly certified in accordance with the Guide for the Control of Molluscan Shellfish.

2. 95% of certified dealers must be evaluated with an inspection frequency, which is compliant with the current Guide for the Control of Molluscan Shellfish.

3. Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

4. 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 administrative action was taken.

5. All critical deficiencies have been addressed in accordance with the Guide for the Control of Molluscan Shellfish.

PUBLIC HEALTH SIGNIFICANCE: Provide guidance to state programs and the FDA in evaluation of the inspection program element of state shellfish sanitation control programs.

COST ESTIMATE: Not known.

ACTION BY 2001 TASK FORCE II: Recommended adoption of 01-225 as amended:

B.6. – STATE INSPECTION PROGRAM EVALUATION CRITERIA

FDA should at a minimum include the following criteria in evaluating the plant inspection element of a state shellfish sanitation program:

1. All dealers are required to be properly certified in accordance with the Guide for the Control of Molluscan Shellfish.

2. 95% of certified dealers must be evaluated with an inspection frequency, which is compliant with the current Guide for the Control of Molluscan Shellfish.

3. Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.

4. 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 administrative action was taken.

5. All critical deficiencies have been addressed in accordance with the Guide for the Control of Molluscan Shellfish. Recommended further that FDA report back on the effectiveness of these criteria to the 2003 Spring Executive Board meeting.

Task Force II further recommended the following:

1) The FDA report back on the effectiveness of these criteria to the 2003 Spring Executive Board Meeting.
2) An effective date of October 1, 2001 and an expedited FDA approval.

ACTION BY 2001 GENERAL ASSEMBLY: Adopted recommendation of 2001 Task Force II.

ACTION BY USFDA: Concurred with Conference action.

Issue 00-201

This issue was referred back to the ISSC V*ibrio vulnificus* Subcommittee following its marginal defeat at the 2000 ISSC. While FDA was disappointed that the 2000 Conference voted to refer Issue 00-201 back to committee, we believe the dedicated efforts of the *Vibrio vulnificus* Subcommittee over the ensuing year resulted in ISSC adoption of a stronger and more workable plan to reduce *Vibrio vulnificus* illnesses associated with raw shellfish consumption. Issue 00-201 was designed to reduce *Vibrio vulnificus* septicemia illnesses through post harvest treatment (PHT) processing, consumer education, and, if necessary, mandatory harvesting and/or processing controls. FDA looks forward to working with states as they develop and implement *Vibrio vulnificus* management plans. We also look forward to our continued participation on the ISSC *Vibrio* Management Committee (VMC*), Vibrio vulnificus* Subcommittee, and *Vibrio vulnificus* Education Subcommittee to implement measures (including data collection, data analysis, and development of annual work plans by the VMC) set forth in the "*Vibrio vulnificus* Management Guidance Document" which was adopted as part of Issue 00-201.

During review of Issue 00-201, FDA noted that adopted in the third sentence of Chapter II.@.04(C)(5) did not include alternatives (e) and (f) of 04(C)(6) should the 40% illness reduction goal not be achieved. It is our understanding that alternatives (e) and (f), which appear to have been inadvertently omitted, will be considered at the January meeting of the ISSC Executive Board for inclusion as alternatives in 04(C)(5).

Issues 00-204, 00-205, and 00-206:

FDA does not concur with action taken by the Conference on Issues 00-204, 00-205, and 00-206. We recommend that these three issues be returned to an appropriate committee of the Conference for further consideration. FDA further recommends that these issues be appointed to the same committee to which Issue 99-209 is referred.

Efforts by the ISSC are needed to establish science based time/temperature controls consistent with HACCP and the defining of critical control points and critical limits that reasonably assure food safety. Issue 00-204, Issue 00-205, and Issue 00-206, each address a particular time/temperature concern worthy of deliberation in the full context of Model Ordinance time/temperature controls. We urge that they be reviewed jointly, along with Issue 99-209, as part of an overall effort by the ISSC to more clearly define shellfish dealer and harvester time/temperature requirements essential to controlling pathogen growth and ensuring product safety. This effort could be similar to that of the 1996 ISSC Tagging Committee to comprehensively review tagging and related requirements of the NSSP.

Issue 01-220:

FDA does not concur with Conference action to adopt Issue 01-220. New ultraviolet bulbs (UV) do not always produce the desired level of disinfection even though the bulb is checked and is found to produce the manufactures rated intensity. Following bulb replacement, the only way to determine the ability of the UV system to adequately disinfect process water under the conditions of operation is to conduct sampling. Once the ability of the UV system to accomplish the desired result has been verified, additional samples, beyond required weekly samples, are not necessary unless the conditions of operation are modified. UV bulb replacement would qualify as a modification of the conditions under which the efficacy of the UV system was verified. Consequently, system water would need to be tested following bulb replacement.

Issue 01-224:

FDA concurs with Conference action to adopt Issue 01-224 even though an important aspect of it was referred to committee for consideration at the next meeting. Issue 01-224 specifically outlined four recommendations for adoption, however only three were adopted. The forth, recommendation number 4, which was referred to an appropriate committee, would have provided for identification, in the Interstate Certified Shellfish Shippers List

(ICSSL), of firms having an approved post harvest treatment process. FDA considers the ability to identify such firms in the shippers list as an important component of a comprehensive NSSP PHT program. We firmly believe that such a measure provides an important incentive to processors who currently use or who are considering installation of, PHT processes to reduce the presence of specific pathogens.