Proposal Subject: Laboratory Evaluations

Specific NSSP Guide Reference: Model Ordinance Chapter III. Laboratory @.01 Quality Assurance

Text of Proposal/ Requested Action Model Ordinance Chapter III. Laboratory @.01 Quality Assurance

A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer ~~(LEO)~~ in accordance with the requirements established under the NSSP.

B. State Program ~~Requirements~~ Responsibilities. The Authority shall ~~assure~~ ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. Accordingly the
Authority shall:

(1) Require laboratories to develop a written quality assurance plan that:

(a)

(b)

(c) Describes all procedures and methods used to ~~collect, maintain, transport and~~ analyze samples;

(d)

(e)

(f) ~~Provides a quality assessment program to demonstrate laboratory and analyst competence. At a minimum this program must~~ includes an annual internal assessment and ~~triennial onsite laboratory evaluations conducted by either FDA laboratory evaluation officers, and annual internal laboratory audits. For microbiological laboratories,~~ requires participation in a recognized ~~the~~ annual ~~FDA sponsored~~ proficiency test program~~s is also required~~ (FDA, NELEOM, etc.)~~.~~ ~~; and~~

(g) Requires corrective action for any deficiencies found in the laboratory quality assurance program

(2) Require~~s~~ laboratories to implement their quality assurance plan;

(3)

(4) ~~Require triennial or more frequent evaluations of all laboratories which conduct both microbial and marine biotoxin analyses used to officially support the state shellfish program;~~Require laboratories to participate in the laboratory evaluation process;~~and~~

~~(5) Require a laboratory to be re-evaluated when any major changes in personnel ,workload, or facilities occur and when a laboratory is found in~~
nonconformance. Inform FDA Shellfish Laboratory Evaluation Officers and/or the State Shellfish Laboratory Evaluation Officer as appropriate of major changes in laboratory personnel, laboratory workload or laboratory facilities; and

(6) Require corrective action for any deficiencies/nonconformities found in the quality assurance program, laboratory operations and laboratory performance.

~~C.~~ FDA Responsibilities. The FDA will ensure that all laboratories

generating data in support of the NSSP will be evaluated at a minimum frequency of once every three (3) years. ~~An FDA certified State Shellfish Laboratory Officer may evaluate laboratories in a different State under a memorandum of understanding agreement between the States and the FDA. The agreement shall be consistent with NSSP requirements.~~

(1) Evaluations will be conducted by either an FDA Shellfish Laboratory Evaluation Officer or an FDA certified State Shellfish Laboratory Evaluation Officer as appropriate. Normally the initial evaluation of a laboratory will be conducted by FDA

(2) Evaluations are generally onsite but can under certain circumstances be by desk audit (evaluation follow-up, action plan monitoring, nonconformity corrections, major changes in personnel, workload or facilities, etc.

D. Laboratory Evaluations.

(1) Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists~~,~~ found in the Guidance documents Chapter II Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.

(a) Conforms. In order to achieve or maintain ~~its~~ conforms status under the NSSP, a laboratory ~~shall~~ must meet the following ~~requirements under the NSSP standardized~~ laboratory evaluation criteria:

(i) No critical nonconformities in the microbiological or marine Biotoxin (PSP or NSP) component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(ii) Not more than twelve (12) key nonconformities ~~for~~ in the microbiological component or five (5) ~~for~~ in the ~~paralytic shellfish poisoning~~ marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(iii) Not more than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total in ~~for~~for the ~~paralytic shellfish poisoning~~ marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must ~~(~~not ~~to~~ exceed the numerical limits established for either the critical ~~and~~ or key criteria~~)~~; and

(iv) No repeat key nonconformities have been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(b) Provisionally Conforms. In order to ~~achieve~~ be deemed provisionally conforming ~~status~~ under the NSSP, a laboratory ~~shall~~ must meet the following ~~requirements under the NSSP standardized microbiological~~ laboratory evaluation criteria:

(i) Not more than three (3) critical nonconformities ~~for~~ in the microbiological component or two (2) ~~for~~ in the marine Biotoxin (PSP or NSP) ~~paralytic shellfish poisoning~~ components have been identified using the

appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(ii) Not more than twelve (12) key nonconformities ~~for~~ in the microbiological component or five (5) ~~for~~ in the marine Biotoxin (PSP or NSP) ~~paralytic shellfish poisoning~~ components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, and;

(iii) Not more than seventeen (17) critical, key and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and,

(iv) Not more than one (1) repeat ~~K~~key nonconformity has been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(c) Nonconformance. When a laboratory exceeds the following criteria, ~~the laboratory shall~~ it will be determined to be in nonconformance:

(i) More than three (3) critical nonconformities ~~for~~ in the microbiological component or two (2) ~~for paralytic shellfish poisoning~~ in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, or;

(ii) More than twelve (12) key nonconformities ~~for~~ in the microbiological component or five (5) ~~for paralytic shellfish poisoning~~ in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, or;

(iii) More than seventeen (17) critical, key and other nonconformities in total ~~for~~ in the microbiological component or more than nine (9) critical, key and other nonconformities in total ~~for paralytic shellfish poisoning~~ in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist, or;

(iv) One (1) or more repeat critical or two (2) or more repeat key nonconformities have been identified in consecutive evaluations in either the microbiological or marine Biotoxin components using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

E. Time Limit on Laboratory Status.

(1) Conforming Status. A laboratory found to be in conforming status for either the microbiological or marine Biotoxin component or for both components has up to ninety (90) days to successfully correct all nonconformities noted in ~~the evaluation~~ each component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory's status

will ~~shall~~ be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory will ~~is~~ no longer be acceptable for use in support of the NSSP for the laboratory component in question

(2) Provisionally Conforms Status. A laboratory found to be in provisionally conforming status for either the microbiological or marine Biotoxin component or for both components has up to sixty (60) days to successfully correct all nonconformities found in each provisionally conforming component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory will ~~shall~~ be assigned ~~a~~ the following status ~~of~~ for the laboratory component(s) in question:

(a) Conforms if all critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated;

(b) Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluated. As a result, data being generated by the laboratory ~~is~~ will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

(3) Nonconformance

(a) Upon a determination of nonconforming status in either the microbiological or marine Biotoxin component or in both components the laboratory has up to thirty (30) days to demonstrate successful correction of all noconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will ~~shall~~ continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory component(s) will ~~is no longer~~ continue to be unacceptable ~~acceptable~~ for use in support of the NSSP.

(b) When a laboratory is found to be nonconforming in either the microbiological or marine Biotoxin component or in both components ~~either~~ for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority ~~shall~~ will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP.

(c) ~~When all critical and key nonconformities have been successful corrected by a nonconforming laboratory;~~ for each laboratory component evaluated, the laboratory will be ~~evaluated~~ reevaluated either on-site or through a ~~careful review of appropriate documentation~~ thorough desk audit as determined by the FDA Shellfish Laboratory Evaluation Officer and the FDA certified State Shellfish Laboratory Evaluation Officer ~~LEO~~ if one is utilized by the State. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP for the laboratory

components in question.

F. ~~Laboratory Services for Depuration~~, Wet Storage and Post-Harvest Processors. For any laboratory providing analytical testing services for depuration, wet storage or Post Harvest Processing (PHP) ~~the quality assurance program (e.g. water quality) including end product testing of any depuration processor,~~ initial and subsequent triennial evaluations will be required and conducted in accordance with @.01 and @.02 of this Chapter by an FDA Shellfish Laboratory Evaluation Officer or an FDA certified State Shellfish Laboratory Evaluation Officer as appropriate. It is understood that academic laboratories involved in PHP Validation or Verification have special circumstances such as extended periods of inactivity resulting from university schedules or funding constraints; however, written documentation of Quality Control practices will be required for time periods in which they are preparing for or actively participating in a PHP validation or verification. Times in which the lab is inactive can be explained with a not applicable notation.

~~a. The Authority shall:~~

~~A. Require the annual inspection of the laboratory in accordance with .01 and .02 of this Chapter; and~~

~~B. Require the laboratory to retain its records for a minimum of the previous two (2) years.~~

Public Health Significance:

This proposal updates and clarifies the roles and responsibilities of the state and the FDA in the laboratory evaluation process. It also clarifies how laboratory status is determined and its effect on the acceptability of the data for use in the NSSP.

In the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter XVI. Post-Harvest Processing (PHP) it states that if a dealer elects to utilize a PHP for the purpose of making safety added labeling claims they must conduct a validation study to demonstrate the ability of the PHP to reduce the target pathogen(s) to acceptable levels. Specifics on target levels and approved methods of detection for pathogens are found in the Model Ordinance. All laboratory analysis must be performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents. Results of the validation study should be submitted in the following format for review and consideration by state and federal shellfish control authorities. For validation of Vibrio vulnificus or *Vibrio parahaemolyticus* methods, checklist may be used as a guide.

Cost Information (if available):

NA

Action by 2013 Task Force I

Recommended adoption of Proposal 13-102 as submitted.

Action by 2013 General Assembly

Adopted recommendation of 2013 Task Force I on Proposal 13-102.

Action by FDA May 5, 2014

Concurred with Conference action on Proposal 13-102.