Proposal Subject: Use of Analytical Methods Other than NSSP Methods

Specific NSSP Guide Reference: 2009 NSSP Section II Model Ordinance Chapter III Laboratory @ .02 Methods, Paragraphs A, C, D (1) and (2)

Text of Proposal/ Requested Action Revise Chapter III @.02 Methods, Paragraphs A, C and D as follows.

Chapter III @ .02 Methods

A. Microbiological. Methods~~, practices, and procedures~~ for the analyses of shellfish and shellfish growing or harvest waters shall be:

(1) the Approved NSSP M~~m~~ethods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests;

(2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

B. Chemical and Physical.

(1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:

(a) Be the current AOAC or APHA method for all physical and chemical measurements; and

(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.

(2) When there is an immediate or ongoing critical need for a Method and no Approved NSSP Method exist, the following may be used:

(a) A Validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

~~(2) When an AOAC or APHA method is not available, EPA methods may be used.~~

~~(3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.~~

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins : and

(2) The current APHA method used in the bioassay for *Karenia brevis* toxins; or

(3) Approved NSSP Methods validated for use ~~in the National Shellfish Sanitation Program~~ under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

(4) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

D. Emergency Use ~~Emerging~~ Methods.

(1) When there is an immediate or critical need and no Approved NSSP ~~approved m~~ Method~~s~~ exists, ~~and~~ the ISSC Executive Board may grant interim approval to ~~considers allowing~~ an unapproved or non-validated method to be used for a specific purpose.~~,~~ ~~t~~ The following minimum requirements ~~as the Lab Method Review Committee Advisory for Emerging Methods~~ will be provided to the Executive Board prior to granted interim approval ~~and shall contain the following criteria~~:

(a) Name of Method
(b) Date of Submission
(c) Specific purpose or intent of the method for use in the NSSP
(d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method
(e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable
(f) Any peer reviewed articles detailing the method
(g) Name of developer(s)~~/~~ or SSCA submitter~~s~~
(h) Developer/submitter contact information

(2) Within two years of Executive Board interim approval ~~the initial allowed use of~~ the Emergency Use M~~m~~ethod, the entire Single Lab Validation Protocol should be submitted. The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

Public Health Significance:

Cost Information (if available): None

Action by 2011 Laboratory Methods Review Committee Recommended adoption of Proposal 11-104 as amended.

B. Microbiological. Methods for the analyses of shellfish and shellfish growing or harvest waters shall be:

(1) the Approved NSSP Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests;

(2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;
(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

B. Chemical and Physical.

(1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:

(a) Be the current AOAC or APHA method for all physical and chemical measurements; and
(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.

(2) When there is an immediate or ongoing critical need for a Method and no Approved NSSP Method exist, the following may be used:

(a) A Validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins : and

(2) The current APHA method used in the bioassay for *Karenia brevis* toxins; or

(3) Approved NSSP Methods validated for use under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

(4) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to .02 D. (1) and (2) below.

D. Emergency Use Methods.

(1) When there is an immediate or critical need and no Approved NSSP Method exists, ~~the ISSC Executive Board may grant interim approval to~~ an unapproved or non-validated method ~~to~~may be used for a specific purpose provided that~~. The following minimum requirements will be provided to the Executive Board prior to granted interim approval~~ :

(a) The appropriate FDA Regional Office is notified within a reasonable period of time regarding the method employed; and

(b) The ISSC Executive Board is notified within a reasonable period of time regarding the method employed.

(2) When it is necessary to continue the use of the emergency method employed under D. (1) beyond the initial critical need, then the following minimum criteria shall be provided to the ISSC Executive Board for interim approval:

(a) Name of Method

(b) Date of Submission

(c) Specific purpose or intent of the method for use in the NSSP

(d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method

(e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable

(f) Any peer reviewed articles detailing the method

(g) Name of developer(s) or SSCA submitter~~s~~

(h) Developer/submitter contact information

(~~2~~3) Within two years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

Action by 2011 Task Force III Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 11-104.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-104.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-104.