

Proposal Subject: Revisions to Chapter III. Requirements for the Authority

Specific NSSP Guide Reference: 2011 NSSP Guide Section II. Model Ordinance Chapter III. Laboratory

Text of Proposal/ Requested Action @.02 Methods

- A. 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 .11 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. Methods for the analyses of shellfish and shellfish 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 cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. ~~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) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings.
 - (3) 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.

- C. Biotoxin. Methods for the analyses of shellfish and shellfish 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 cited in the Guidance Documents Chapter II. Growing Areas .11 Approved National Shellfish Sanitation Program Laboratory Tests. ~~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 .11 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, an unapproved or non-validated method may be used for a specific purpose provided that:
 - (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 Shellfish Control Authority submitter.
 - (h) Developer/submitter contact information.
 - (3) Within two (2) years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Laboratory Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

**Public Health
Significance:**

This revision to Chapter III. Laboratory is necessary to clarify and guide users to the location within the Guidance Documents that lists the approved NSSP laboratory tests in .11 Approved NSSP Laboratory Tests. All approved laboratory tests are now listed in Table .11 Approved NSSP Laboratory Tests with the Guidance Document.

**Cost Information
(if available):**

**Action by 2013
Task Force**

Recommended adoption of Proposal 13-119 as amended.

@.02 Methods.

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 - (2) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings.
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 - (g) Name of developer(s) or Shellfish Control Authority submitter.
 - (h) Developer/submitter contact information.
 - (3) Within two (2) years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Laboratory Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

**Action by 2013
General Assembly**

Adopted recommendation of Task Force I on Proposal 13-119.

**Action by FDA
May 5, 2014**

Concurred with Conference action on Proposal 13-119.