Proposal Subject: Procedure for Handling and Disseminating Interpretations of the Manual by FDA

Specific NSSP Guide Reference: ISSC Constitution, Bylaws, and Procedures
Procedure XII.

Text of Proposal/ Requested Action: PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING

INTERPRETATIONS OF THE NSSP GUIDE FOR THE CONTROL OF

MOLLUSCAN SHELLFISH~~MANUAL~~ BY FDA.

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

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

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

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

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

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

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

Subdivision d. An opinion on resolving the problem. Include

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

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

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

Subdivision a. Within sixty (60) days of acknowledgment of the letter, the Office of Food Safety~~Field Programs~~ will provide a draft proposal to the FDA Regional Offices, the ISSC Executive Director, and DFSR for comment. The ISSC Executive Director shall distribute the draft proposal to the requestor and ISSC members from states, industry, and the general public.

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

Section 5. Comments on the Draft Interpretation.

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

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

Section 6. Action on Draft Interpretation Comments.

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

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

Subdivision ii. Issuing the final interpretation without revision.

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

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

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

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

Subdivision c. Final interpretation shall be incorporated into the NSSP Guide for the Control of Molluscan Shellfish.

Public Health Significance:

Cost Information (if available):

Action by 2011 Task Force III Recommended adoption of Proposal 11-304 as submitted.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-304.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-304.