Proposal Number: 03-200

Proposal Subject

Plant Inspections

Specific NSSP Guide Reference

NSSP Guide Model Ordinance Chapter I. Shellfish Sanitation Program

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Text of Proposal/ Requested Action

- F. Inspections.
 - (1) After any person is certified, the Authority shall make unannounced inspections of all shucker-packers, and all shellstock shippers that have scheduled business hours. Inspections may be scheduled for shellstock shippers that operate intermittently or do not have scheduled business hours. The inspections shall be performed: of the dealers facilities:
 - (a) During periods of activity; and
 - (b) At the following minimum frequencies:

Public Health Significance

This change should have minimal impact to public health. It is an effort to use state resources in the most efficient and effective manner possible.

Cost Information (if available)

This change will result in significant savings to state authorities that have shellstock shippers that do not have regularly scheduled business hours. Shellfish authorities can spend a considerable amount of time attempting unannounced inspections in remote locations for shellstock shippers that operate intermittently.

Action by 2003 Task Force I

Recommended adoption of Proposal 03-200 as amended:

- F. Inspections.
 - (1) After any person is certified, the Authority shall make unannounced inspections of all shucker packers, and all shellstock shippers dealers. For those dealers who work infrequently or who have unscheduled business hours inspections may be scheduled that have scheduled business hours. Inspections may be scheduled for shellstock shippers that operate intermittently or do not have scheduled business hours. The inspections shall be performed:
 - (a) During periods of activity; and
 - (b) At the following minimum frequencies

Action by 2003 General Assembly

Adopted recommendation of 2003 Task Force II.

Action by USFDA

Did not concur with Conference action and recommended this Proposal be referred back to the Conference for deliberation by an appropriate committee. FDA offered the following comments:

FDA does not concur with action by the Conference to adopt Proposal 03-200. Proposal 03-200 provides for **scheduled** inspections at shellfish firms that may operate intermittently or that may have infrequent business house. We recommend that this proposal be referred back to the Conference for deliberation by an appropriate committee.

FDA recognizes that there are instances when scheduling an inspection is necessary due to the unusual operating schedule of a firm. FDA believes that state shellfish authorities currently have the discretion to schedule inspections where unannounced visits have not been possible. Rather than establishing Model Ordinance language to address the infrequent occurrence of such situations, FDA supports handling them on a case-by-case basis where sound judgment can prevail. Of course, justification for conducting a scheduled inspection at a shellfish dealer must be documented in the central file.

Action by 2004 ISSC Executive Board

Requested FDA develop an NSSP interpretation to explain existing state flexibility related to announced inspections.

Action by 2005 Task Force II

No action required.

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Rationale – Proposal 03-200 has been resolved by action of the Executive Board. The USFDA developed an interpretation and all comments received were supportive.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.