Proposal Subject: Approval of Shellfish Shippers/Reshippers in Non-Participatory States

Specific NSSP Guide Reference:

- 1. ISSC Constitution, Bylaws, and Procedures Definitions
- 2. NSSP Guide Section II. Model Ordinance Definitions B. Definition of Terms (7)
- 3. NSSP Guide Section II. Model Ordinance Chapter I. Shellfish Sanitation Program @.01 Administration B. State Laws & Regulations
- 4. NSSP Guide Section II. Model Ordinance Chapter I. Shellfish Sanitation Program @.02 Dealer Certification A. General (1)

Text of Proposal/ Requested Action

1. ISSC Constitution, Bylaws, and Procedures Definitions

Add a new definition:

NON-PARTICIPATING STATE – any state that chooses not to participate in the NSSP. [Subsequent definitions will need to be renumbered.]

- 2. NSSP Guide Section II. Model Ordinance Definition of Terms B. Definition of Terms
 - (7) Authority means the State or local shellfish control authority or authorities or its designated agents, which are responsible for the enforcement of this code.

 In NON-PARTICIPATING STATES, Authority shall mean the FDA Office of Seafood or its designated agents.
- 3. NSSP Guide Section II. Model Ordinance Chapter I. Shellfish Sanitation Program @.01 Administration
 - B. State Laws and Regulations.

The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A. If the Authority is the FDA Office of Seafood, the laws and regulations shall be the NSSP Model Ordinance.

- 4. NSSP Guide Section II. Model Ordinance Chapter I. Shellfish Sanitation Program @.02 Dealer Certification A. General (1)
 - (1) A person requesting certification shall be subject to a comprehensive, onsite inspection and meet the criteria in §B. or §C., as appropriate. The plant inspection shall be conducted by the state shellfish standardization inspector, using the appropriate inspection form, within the 120 day period. In NON-PARTICIPATING STATES, the inspection shall be conducted by an agent of the FDA Office of Seafood.

Certain seafood products are controlled under the National Shellfish Sanitation Act (NSSA), which includes the Interstate Certified Shellfish Shippers List (ICSSL). Any business or individual involved in the sale or resale of shellfish across a state or international border must be included in the ICSSL. The FDA has formalized this in the FDA Model Food Code for a number of years in Section 3-201.15 (B) that states "Molluscan Shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers Guide".

While the rules and requirements of the Shellfish Sanitation Act are federal in scope, they are administered by the individual states. Participation by each state is voluntary- there is

no requirement that a state administer the program, and in fact only 35 states plus the District of Columbia currently do so. Any food distributor or wholesaler located in the remaining 15 states that do not participate cannot be listed on the ICSSL, and therefore cannot legally ship products covered by this act across state lines.

While there are several possible solutions, the most efficient appears to be allowing FDA Shellfish Specialists to approve facilities in states that do not participate. While the FDA prefers that all states participate, non-producing states have little incentive to incur the expense and time of training (or simply do not have the personnel). The changes below are designed to change the regulations to allow such activities by the FDA.

Public Health Significance:

Currently, a shipper or reshipper in a non-participating state has no recourse. The only option is to not ship across any state lines, thereby causing a loss of business both directly and indirectly.

Or, a shipper can ignore the law and hope they do not get caught. This latter recourse means shellfish are being shipped interstate from facilities that have not been approved for such actions This reduces the effectiveness of the law, designed to ensure safe shellfish handling from harvest through consumption.

Further, the flaw in this rule, which sets a requirement but does not ensure the ability to meet such requirement, weakens the overall opportunity for industry and regulators to work as partners in protecting public health. Both the International Food Distributors Association (IFDA) and the National Conference for Food Protection (NCFP) are supporting this issue.

Therefore we are requesting that ISSC work with the FDA so that any reshipper desiring to move product across state lines is afforded the opportunity for inspection and inclusion on the ICSSL.

Cost Information (if available):

The only cost is to the FDA which will be required to provide inspections to firms in non-participating states.

Action by 2009 Task Force III

Recommended referral of Proposal 09-300 to an appropriate committee as determined by the Conference Chairman.

Action by 2009 General Assembly

Voted no action on Proposal 09-300.

Action by USFDA 02/16/2010

Concurred with Conference action on Proposal 09-300.