Proposal Subject:

Exemption for Distribution Centers Operating in States Not Participating in the NSSP that Only Reship Processed and Packaged Shellfish from Certified Shippers Listed in the ICSSL

Specific NSSP Guide Reference:

NSSP Guide Section II. Model Ordinance Chapter XIV. Reshipping

.03 Other Model Ordinance Requirements

Text of Proposal/ Requested Action

F. Shellfish Storage and Handling.

- (1) The dealer shall not:
 - (a) Commingle, sort, or repack shellstock or shucked shellfish; or **[K]**
 - (b) Remove or alter any existing tag or label. [K]
- (2) A dealer whose activity consists of trucks only shall:
 - (a) Have his own facility for the storage of shellfish; or [K]
 - (b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and **[K]**
 - (c) Have a permanent business address at which records are maintained and inspections can be performed. **[K]**

The Conference for Food Protection (CFP) approved CFP Issue 2008-I-014, Interstate Shipment of Shellfish at their 2008 conference. The issue recommended that the Conference send a letter to the FDA requesting that:

- 1. The FDA work with the NSSP to remove reshippers from the ICSSL listing requirement. Shellfish will still need to come from an approved source for harvesting/packing, but once the product is packaged and shipped, the requirement for reshippers (i.e., distribution facilities performing no handling or processing) to be listed on the ICSSL is dropped. (Note: annual verification of a seafood HACCP program still remains); or
- 2. The FDA provides direct inspection coverage and listing for reshippers in the [then]17 states not currently participating; and/or
- 3. The FDA accepts an inspection from an accredited 3rd-party auditing firm for distributors/reshippers within the 17 non-participating states, and provides listing on the ICSSL.

The CFP Executive Board, in discussions with the FDA, realized that the issue involves procedures approved under the NSSP and the administration of the ICSSL and therefore this issue is being submitted to the 2009 ISSC as a proposal.

Public Health Significance:

The following information was presented in support of the issue that was submitted to the 2008 Conference for Food Protection (CFP) and was considered by CFP Council 1 during deliberation with the conclusion being the recommendation that is being submitted to the ISSC per the CFP Executive Board recommendations:

Certain seafood products are controlled under the National Shellfish Sanitation Program (NSSP), 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 National Shellfish Sanitation Program are federal in scope, they are administered by the individual states. Participation by each state is voluntary, i.e., there is no requirement that a state administer the program, and in fact only 67% of states plus the District of Columbia currently do so with those states involved with growing, harvesting and processing shellfish comprising the predominant percentage of members. Any food distributor or wholesaler located in the states that choose not to participate in the ICSSL for one reason or another, cannot be listed on the ICSSL, and therefore cannot legally ship products covered by this act across state lines.

The laws requiring that purveyors of shellfish must have in place adequate and verifiable food safety measures for inclusion on the ICSSL have worked well to improve the safety of seafood in the U.S. The list itself provides an excellent clearinghouse for registered shellfish shippers by acting as a repository for shellfish dealers and shippers with certified HACCP food safety programs in place. The current system does not recognize the major food distribution centers operating under regulated food safety and sanitation program apart from the NSSP that act as nothing more than a throughput of shellfish that have already met sanitation and food safety requirements under the NSSP. These products are passed through to customers without any additional handling or processing and under regulated time-temperature controls in other non-NSSP programs since they are never opened. Customers receiving these products can verify the certified dealer that initially shipped the product, assure all required shellfish tags, product labeling to meet compliance with the NSSP remain intact and the product delivered under required temperatures set by Law. The Distribution Centers maintain excellent food safety and sanitation programs to include operating under the Seafood HACCP program with oversight from Federal, State or local regulatory officials as applicable. There only discrepancy is that, through no fault of their own, they are operating in a state that has not voluntarily participated in the NSSP from distributing across state lines regardless of the safety of the product.

This issue does not propose elimination of the ICSSL, nor does it recommend that HACCP/food safety standards and controls be eliminated. Therefore, there is no "public health" impact. Eliminating this discrepancy and allowing all legally permitted Distribution Centers to distribute unopened shellfish products without being listed in the ICSSL will not create more of a risk since the same standards are required and met whether a state participates or not.

Cost Information (if available):

Action by 2009 Task Force III:

Recommended referral of Proposal 09-227 and the substitute (see below), which was submitted by the presenter, to an appropriate Committee as determined by the Conference Chairman with instructions to consider the impact this proposal would have on non-producing state participation in the ISSC and the NSSP.

Proposal Subject:

Alternate means of Certification of Shellstock reshippers operating in states not participating in the NSSP that only reship processed and packaged shellfish from certified shippers listed in the ICSSL.

Specific NSSP Guide Reference:

NSSP Guide Section II. Model Ordinance Chapter XIV. Reshipping

Text of Proposal/ Requested Action

The Conference for Food Protection (CFP) believes that consumers throughout the United States should be able to enjoy the benefits of safe, wholesome certified raw molluscan shellfish. We also believe that any business that complies with the requirements for certification and desires to be listed in the ICSSL should be listed. However, consumers are being denied the opportunity to consume certified shellfish and many businesses are unable to sell certified shellfish because the local regulatory authority does not verify compliance with the NSSP requirements and does not recommend to FDA the listing of any firms in the ICSSL. Unfortunately, some firms choose, of necessity, to handle raw molluscan shellfish without being certified. This puts consumers and retailers at risk because there is no assurance that the shellfish they consume is safe and wholesome. It harms competitors who choose not to handle raw molluscan shellfish in facilities that are not certified even though they would do so if certification were available.

The CFP approved Issue 2008-I-014, Interstate Shipment of Shellfish at their 2008 conference. The issue recommended that the Conference send a letter to the FDA requesting that:

- 1. The FDA work with the NSSP to remove reshippers from the ICSSL listing requirement. Shellfish will still need to come from an approved source for harvesting/packing, but once the product is packaged and shipped, the requirement for reshippers (i.e., distribution facilities performing no handling or processing) to be listed on the ICSSL is dropped. (Note: annual verification of a seafood HACCP program still remains); or
- 2. The FDA provides direct inspection coverage and listing for reshippers in the [then]17 states not currently participating; and/or
- 3. The FDA accepts an inspection from an accredited 3rd-party auditing firm for distributors/reshippers within the 17 non-participating states, and provides listing on the ICSSL.

Therefore, CFP is now coming before the ISSC for the purpose of asking that the NSSP Guidelines be amended to provide for a method of certification and listing of firms (shellstock reshippers in particular) which are located in states that do not have a shellfish sanitation program. The CFP does not presume to suggest specific amendments to the NSSP Guidelines to accomplish this because the NSSP Guidelines are under the exclusive purview of the ISSC, which has far greater knowledge and expertise in this area than CFP.

Public Health Significance:

Certain seafood products are controlled under the National Shellfish Sanitation Program (NSSP), 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".

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This issue does not propose elimination of the ICSSL, nor does it recommend that HACCP/food safety standards and controls be eliminated. Therefore, there is no "public health" impact. Eliminating this discrepancy and allowing all legally permitted Distribution Centers to distribute unopened shellfish products without being listed in the ICSSL will not create more of a risk since the same standards are required and met whether a state participates or not.

Cost Information (if available):

N/A

Action by 2009 General Assembly Voted no action on Proposal 09-227.

Action by USFDA 02/16/2010

Concurred with Conference action on Proposal 09-227.