

Proposal Subject: Time Requirement for Achieving Internal Oyster Temperature of 50°F (10°C)

Specific NSSP Guide Reference: NSSP Guide Section II. Model Ordinance
Chapter II. Risk Assessment and Risk Management
@.05 *Vibrio parahaemolyticus* Control Plan

Text of Proposal/ Requested Action Insert new item and re-letter subsequent items.

B. Control Plan

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more...

(b) Implement one or more...

(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer’s HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 or less as determined by the Authority hours of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled “for shucking only”, or other means to allow the hazard to be addressed by further processing.

~~(d)~~ (d) Evaluate the effectiveness...

~~(e)~~ (e) Modify the Control Plan when...

~~(f)~~ (f) Optional cost benefits analysis...

Public Health Significance:

Vibrio parahaemolyticus is the leading cause of bacterial illnesses associated with consumption of raw molluscan shellfish in the U.S. The ISSC adopted a *Vibrio parahaemolyticus* Control Plan for oysters in August 2007. The Plan was fully implemented by states as of June 20, 2008. The major control measure under the plan is a reduction in the time between exposure of oysters to air and initial placement into refrigeration. Once placed under refrigeration, the only Model Ordinance requirement is that the refrigeration unit be maintained at 45°F (7.2°C) or less. There is no requirement for reducing product temperature to a specified level within a specified period of time. The scientific literature indicates that *Vibrio parahaemolyticus* can grow in oysters at temperatures above 50°F (10°C). The FDA *Vibrio parahaemolyticus* Risk Assessment assumes that oysters are cooled to 50°F (10°C) within 10 hours after placement in refrigeration and that controlling growth after initial refrigeration is a key factor affecting the risk of illness. However, cooling systems for shellstock are diverse and little is known about their individual cooling performance under the variety of circumstances in which they are used. According to scientists involved in refrigeration technology, the time required to drop product temperature to 50°F (10°C) on refrigerated vehicles can take as long as 100 hours depending on initial product temperature. According to manufacturers of refrigerated truck compressors, cooling systems generally used on refrigerated trucks are only intended to maintain product temperature, not reduce it. Therefore, product, such as shellfish, needs to be prechilled to the desired temperature prior to truck loading and

transport. Additionally, the FDA/ISSC 2007 Retail Oyster Study indicated levels of both *Vibrio parahaemolyticus* and *Vibrio vulnificus* frequently exceeded 100,000 MPN per gram, further strengthening the need for mandatory time to temperature requirements following placement under refrigeration.

A major premise of the *Vibrio parahaemolyticus* Control Plan is that 10 hours represents the maximum time to cool oysters to 50°F (10°C). Therefore, it is critical that the Model Ordinance support a system to ensure that the 10 hour cool down time is met. Without measures to ensure that oyster shellstock is cooled to 50°F (10°C) within 10 hours, the level of protection intended by the ISSC, the *Vibrio parahaemolyticus* Control Plan will not be achieved.

**Cost Information
(if available):**

Potential costs associated with this action:

1. Cost to upgrade and operate effective refrigeration systems at processing plants.
2. Loss of product value due to withdrawal from raw consumption market

Potential savings that may result from this proposal include:

1. Reduction in cost to individuals or society from fewer illnesses
2. Avoidance of product recall and loss of consumer confidence associated with recalls and recall press
3. Longer shelf life for properly chilled product
- 4.

**Action by 2009
Task Force II**

Recommended adoption of Proposal 09-209 as submitted.

**Action by 2009
General Assembly**

Adopted recommendation of 2009 Task Force II on Proposal 09-209.

**Action by USFDA
02/16/2010**

Concurred with Conference action on Proposal 09-209.