Proposal Subject Control of *Vibrio parahaemolyticus*

Specific NSSP Guide Reference:

NSSP Guide for the Control of Molluscan Shellfish Model Ordinance

- Chapter XI. Shucking and Packing .01 Critical Control Points A. Receiving Critical Control Point – Critical Limits;
- Chapter XIII. Shellstock Shipping .01 Critical Control Points A. Receiving Critical Control Point – Critical Limits;
- Chapter XV. Depuration .01 Critical Control Points A. Receiving Critical Control Point – Critical Limits

Text of Proposal/ Requested Action

- Chapter XI. Shucking and Packing .01 Critical Control Points A. Receiving Critical Control Point – Critical Limits; and
- Chapter XIII. Shellstock Shipping .01 Critical Control Points A. Receiving Critical Control Point – Critical Limits

Add a new (3) as follows to each of the above referenced chapters:

(3) Harvested, transported, and chilled in a manner that minimizes the likelihood that total *Vibrio parahaemolyticus* levels in the shellfish meats will meet or exceed 10,000 MPN/gram after initial chilling to 45°F or below. This provision shall not apply if any of the following apply:

(a) The occurrence of total *Vibrio parahaemolyticus* levels in the shellfish meats at or above 10,000 MPN/gram after initial chilling to 45°F or below is not reasonably likely to occur in the absence of control for the relevant combination of season, harvest region (e.g., Atlantic Coast, Gulf Coast, Pacific Coast), and harvest method (e.g., dredge, intertidal collection); or

(b) The product is shucked by the dealer; or

(c) The product is labeled "For shucking by a certified dealer;" or

(d) The product is post-harvest treated by the dealer in conformance with Chapter XVI A (1)(b).

- Chapter XV. Depuration .01 Critical Control Points A. Receiving Critical Control Point – Critical Limits

Add a new (4) as follows to the above referenced chapter:

(4) Harvested, transported, and chilled in a manner that minimizes the likelihood that total *Vibrio parahaemolyticus* levels in the shellfish meats will meet or exceed 10,000 MPN/gram after initial chilling to 45°F or below. This provision shall not apply if any of the following apply:

(a) The occurrence of total *Vibrio parahaemolyticus* levels in the shellfish meats at or above 10,000 MPN/gram after initial chilling to 45°F or below is not reasonably likely to occur in the absence of control for the relevant combination of season, harvest region (e.g., Atlantic Coast, Gulf Coast, Pacific Coast), and harvest method (e.g., dredge, intertidal collection); or

(b) The product is shucked by the dealer; or

(c) The product is labeled "For shucking by a certified dealer;" or

(d) The product is post-harvest treated by the dealer in conformance with Chapter XVI A (1)(b).

Public Health Significance

Guidance Document Chapter II.13 of the 2003 Revision of the National Shellfish Sanitation Program (NSSP) "Guide for the Control of Molluscan Shellfish," provides a protocol for reviewing the classification of growing areas from which shellfish meat samples exhibit positive human pathogen isolates in the absence of illness. The guide calls for such areas to be closed if there is an established action level or level of concern for the pathogen. It lists an action level or level of concern for *Vibrio parahaemolyticus* in molluscan shellfish of "levels

equal to or greater than a MPN count of 10,000 per gram and Kanagawa positive or negative." It further states that FDA will consider enforcement action against a shipment of molluscan shellfish if the action level or level of concern is exceeded.

In its April 14, 2005 News Release, entitled, "Foodborne Illnesses Continue Downward Trend: 2010 Health Goals for E. Coli 0157 Reached," the U.S. Department of Health and Human Services summarized the FoodNet data recently published by the Centers for Disease Control and Prevention (CDC) in the Morbidity and Mortality Weekly Report. The report indicates that *Vibrio* infections have increased 47 percent from 1996 to 2004. This is in contrast with the trends for other pathogens during the same period: *E. coli* O157 infections decreased 42 percent; *Campylobacter* infections decreased 31 percent; *Cryptosporidium* dropped 40 percent; and *Yersinia* decreased 45 percent. The report attributes the reductions to a number of government-initiated enhancements to industry's food safety systems, as well as effective consumer awareness programs.

Fifty-two percent of the *Vibrio* infections which were speciated were identified as *V. parahaemolyticus*. It is important to note that FoodNet data do not differentiate between wound infections and foodborne events, shellfish and non-shellfish sources, or commercial and recreational harvest. As a result, the absolute numbers may not accurately describe the magnitude of the *V. parahaemolyticus* issue as it relates to the responsibilities of the U.S. Food and Drug Administration or the members of the Interstate Shellfish Sanitation Conference (ISSC). On the other hand, the trend in the data is a useful indication that present efforts are not fully controlling the hazard. Similar data from the CDC's Cholera and other *Vibrio* Illness Surveillance System (COVISS) and Foodborne Outbreak Reporting System indicate that *Vibrio parahaemolyticus* is an important and continued cause of sporadic cases and outbreaks in the United States.

These data, coupled with FDA's draft risk assessment on *V. parahaemolyticus*, are sufficient to convince FDA that steps must be taken promptly to reduce the risk that raw molluscan shellfish cause *V. parahaemolyticus* infections. FDA is aware that a standard of 10,000 MPN/g *V. parahaemolyticus* in raw molluscan shellfish may not be sufficiently protective in all cases. Nonetheless, the risk assessment concludes that the vast majority of *V. parahaemolyticus* illnesses would be eliminated if it were strictly enforced.

Cost Information (if available)

The following analysis, previous provided by FDA to the ISSC is relevant:

Impacts of Eliminating Shellfish Hazards
David Zorn, FDA
July 2003

The Social Cost of Shellfish Hazards
The cost to society (in terms of medical expenditures, lost work, pain, suffering, etc.) of illnesses, hospitalizations, and deaths associated with *Vibrio parahaemolyticus* is about $20 million to $40 million per year (Zorn, 2002) and for *Vibrio vulnificus* is about $70 million to $140 million per year. The extent to which these can be reduced by treatment options depends on the effectiveness of the treatments, the extent of adoption, and the amount of untreated oysters that are consumed (e.g., recreational harvest).

The Social Cost of Eliminating Shellfish Hazards
The costs of treatment depend on the method of treatment chosen. Because there are different acceptable treatment methods that have different appeal to different types of processors, and because none of these technologies have been broadly implemented for any lengthy period of time the cost of adopting treatment industry-wide is uncertain, but preliminary estimates indicated that the costs would be $30 million or less. (Muth, et al., 2000) These costs underestimate the actual social cost of eliminating shellfish hazards since they do not include the costs of the increased financial burden (reduced incomes/unemployment) on the lives of those involved in producing shellfish (in terms of increased stress, alcoholism, family abuse, etc.) (Kuchler, et al., 1999).

Different technologies have different benefits that may be able offset the costs of adoption. For example, eliminating the need for skilled shuckers and increasing the yield of meat.

It is important to remember that the current time and temperature restrictions are not costless. Treatment would allow industry more flexibility in harvest, handling, and transportation, and reduce monitoring resources of State authorities.

When only Gulf oysters are treated, the Gulf oyster industry suffers economically, while industry in other regions benefit. (Anderson, et al., 1996; Muth, et al., 2002) When oysters from all regions are treated, the differential negative effect on the Gulf industry disappears. (Muth, et al., 2000) Moreover, it is possible that treatment of oysters nationwide that eliminated hazards from both *Vibro* species would increase the demand for oysters in general and possibly the Gulf industry could benefit more than the other regions since the decrease in risk would be significantly greater for Gulf oysters by addressing *V. vulnificus* than for oysters not associated with *V. vulnificus* illnesses.

Anderson, Donald, et al., "Cost of Restrictions on Gulf Oyster Harvesting for Control of Vibrio vulnificus-Caused Disease," 1996.

Kuchler, Fred, et al., "Health Transfers: An Application of Health-Health Analysis to Assess Food Safety Regulations," *Risk*, 1999.

Muth, Mary, et al., "Economic Impacts of Requiring Post-Harvest Treatment of Oysters," 2000.

Muth, Mary, et al., "Effects of Post-Harvest Treatment Requirements on the Markets for Oysters," *Agricultural and Resource Economics Review*, October 2002.

Zorn, David, "Economic Burden of Foodborne Illness from *Vibrio parahaemolyticus* in the United States," 2002.

Action by 2005 Task Force II

Recommended adoption of the following substitute as amended for Proposal 05-214.

Add a new section F to Guidance Documents Chapter IV .03 *Vibrio parahaemolyticus* Interim Control Plan, to read as follows:

F. Risk Communication

If the waters of a state have been confirmed as the original source of oysters associated with ~~one~~ **two** or more *Vibrio parahaemolyticus* illnesses, the Authority should educate all licensed harvesters and shellstock dealers concerning the public health and other advantages of effective cooling of harvested shellstock and encourage that shellstock intended for raw consumption that will not be post-harvest processed in accordance with XVI A(1)(b) be handled in a manner that restricts the growth of *Vibrio parahaemolyticus*. The education package used by the Authority should include an illustration of how effective controls will reduce the risk of *Vibrio parahaemolyticus* illness and should be targeted to the harvest practices of the region.

Action by 2005 General Assembly

Adopted recommendation of 2005 Task Force II.

Action by USFDA

Concurred with Conference action.