

July 7, 2014

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Dear Kevin Smith and Lori LeMaster

The Interstate Shellfish Sanitation Conference (ISSC) has reviewed the Conference for Food Protection (CFP) action on Issue I-025 and offers the following comments for consideration by the CFP and the USFDA.

The background information included in the Public Health Significance of the Issue is misleading. Recent increases in *Vibrio* illnesses are not at all related to *Vibrio vulnificus* (*V.v.*). The increases are associated with the spread of O4:K12 and O4:Kunttypeable strains of *Vibrio parahaemolyticus* (*V.p.*). Historically these strains have caused illnesses in the Pacific northwest, but recently, illnesses have begun to occur on the northeast coast of the United States. The risk of death associated with *V.p.* is overstated. Death from *V.p.* is extremely rare. The rate of illness associated with *V.v.*, the species associated with severe illness and death, has not increased and remains stable at approximately 35 illnesses annually.

The ISSC supports the use of consumer advisories and welcomes efforts to improve their effectiveness. However, the ISSC does not agree that the recommended solution of Issue I-025 would improve effectiveness or reduce illnesses.

The ISSC is continuing to focus efforts to better understand the virulent strains of *V.p.* associated with recent increases in illnesses. The risk of *V.p.* illnesses associated with these virulent strains appears to be a regional problem. There are harvest regions of the U.S. that have not been the source of shellfish associated with increases in reported illnesses. Additionally, the language does not recognize that the risk level is not constant throughout the year. At lower water temperatures the risk of *V.p.* illness greatly diminishes. The proposed language would not be helpful to consumers in identifying raw shellfish that actually pose a higher risk of illness. Additionally, the proposed burden for providing proof of post-harvest processing (PHP) in Section E. is not necessary. Presently the FDA Interstate Certified Shellfish Shippers List (ICSSL) contains the relevant information and shellfish that have been PHP treated are labeled as such. The reference for the analytical method is also inaccurate.

The recommended solution assumes that the relative risk of consumption of raw shellfish is much higher than other animal foods that are consumed raw, undercooked, or not otherwise processed to eliminate pathogens. The recommended solution in the Issue is not the most appropriate way to address relative risk.

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The ISSC recommends that the CFP take no action on Issue I-025 as written. The CFP is encouraged to continue to pursue steps to improve the effectiveness of consumer advisory and compliance with existing temperature control, handling and record keeping requirements at retail and food service establishments. The ISSC offers its assistance in any way that you think appropriate.

Sincerely,



Maryanne Guichard  
Executive Board Chair

/nsd/ccm

cc: ISSC Executive Board  
David McSwane, CFP Executive Director  
Paul DiStefano, USFDA

## Original Issue- 1-025

### Title

Consumer Advisory - Amend Section 3-603.11

### Issue you would like the Conference to consider

The FDA Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the consumer advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from pathogenic *Vibrio* bacteria in raw oysters.

### Public Health Significance

FoodNet data indicates that *Vibrio* illnesses have more than doubled while illnesses from all other major foodborne pathogens have either been stable or decreased. There is also evidence that serious pathogenic *Vibrio* species are becoming more common in raw shellfish. *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico has long posed a well-defined risk of severe illness and death to consumers with compromised immune systems, liver damage, diabetes, the genetic disorder hemochromatosis, and certain gastric disorders. In recent years, a number of *V. vulnificus* cases are associated with oysters harvested along the East Coast. *Vibrio parahaemolyticus* is associated with mild gastroenteritis in persons with healthy immune systems, and can progress to life-threatening infections in persons with pre-existing medical conditions. In 2012, a highly virulent West Coast strain of *V. parahaemolyticus* appeared in East Coast oysters causing the largest oyster-associated outbreak ever recorded along the Atlantic Coast. Outbreaks in 2013 far exceed the count of cases from 2012. Given the increasing number of illnesses and the spread of pathogenic strains to new areas, it is critical that persons have adequate notice of the risk so that they will seek early medical care and inform their doctor they have eaten raw oysters. While the strongest prevention is to require all oysters shipped interstate to be treated post-harvest to eliminate the pathogen, the industry has resisted such requirements. The proposed warning is, therefore, consistent with industry preferences for consumer education in lieu of other controls. It is a critical requirement because other than self-identification, food establishments have no way of recognizing at-risk patrons. To the extent that patrons have adequate information about their own health status, the warnings may reduce the number of illnesses and deaths (with the attendant bad publicity associated with news reports and lawsuits). Additionally, since consumer perceptions can alter choices thus reducing demand, industry interests and public health walk hand-in-hand with providing adequate notice that allows at-risk populations to understand and assess the danger of consuming raw oysters.

### Recommended Solution: The Conference recommends...

that a letter be sent to the FDA recommending the 2013 Food Code be amended with the addition of new consumer advisory language to Section 3-603.11, as follows (new language in underline format):

Section 3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens

(D) Every FOOD ESTABLISHMENT that offers raw oysters shall provide a written warning to any person who orders raw oysters, stating:

**WARNING**

THIS FACILITY OFFERS RAW OYSTERS. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE, CANCER, DIABETES, OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.

(E) Warnings under subsection (D) are not required whenever the FOOD ESTABLISHMENT has received a copy of a current verification letter from the dealer and tags or labels are as required by Section 3-202.18 of this Code demonstrating that the oysters have been subjected to an oyster treatment process sufficient to reduce Vibrio bacteria to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

**Attachments**

- ["Public Health Rationale Raw Oysters" \(2013\)](#)
- ["Increase in Vibrio Illnesses-- CDC" \(2013\)](#)

**Submitter Information**

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