

**Conference for Food Protection
2012 Issue Form**

**Internal Number: 063
Issue: 2012 I-025**

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

All information above the line is for conference use only.

Title:

Addition to Consumer Advisory, Section 3-603.11 of the Model Food Code

Issue you would like the Conference to consider:

The 2009 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 *Vibrio vulnificus* in raw oysters harvested from the Gulf of Mexico. An adequate advisory is modeled in title 17 of the California Code of Regulations § 13675 which provides a basis for the proposed addition to Section 3-603.11.

(<http://www.cdph.ca.gov/pubsforms/Guidelines/Documents/fdb%20Raw%20Oyst%20Sale%20Retail.pdf>)

Public Health Significance:

Vibrio vulnificus in raw oysters harvested from the Gulf of Mexico poses 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. *Vibrio* is associated with mild gastroenteritis in persons with healthy immune systems, and life-threatening infections in persons with pre-existing medical conditions. Each year 30 or more people are diagnosed with *V. vulnificus*-induced septicemia from raw oysters sourced to Gulf Coast waters and approximately half die from the infection. Even with aggressive treatment the case fatality rate is 30 to 40 percent and mortality is 100 percent if a patient is not treated within 72 hours of symptom onset. Because *V. vulnificus* presents as primary septicemia, a common disease with many causes, misdiagnosis almost certainly results in underreporting of the disease. 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 Gulf 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 requesting the 2009 Food Code (as modified by the Supplement issued in 2011), Section 3-603.11, be amended as follows (new language shown with underline):

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 harvested from the Gulf of Mexico (any oyster harvested from the Gulf waters bordering the states of Alabama, Florida, Louisiana, Mississippi, or Texas) shall provide a written warning to any person who orders raw oysters, stating:

WARNING

THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. 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 vulnificus* to an undetectable level, as defined in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 2004 Edition.

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