

July 7, 2014

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CFP Conference Chair
TN Department of Health
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Andrew Johnson Tower, 4th Floor
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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