November 6, 2009

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

We are writing with significant concern regarding the Food and Drug Administration’s (FDA) recently announced intention to “reformulate its policy on control of Vibrio vulnificus in raw molluscan shellfish” (letter from Deputy Director, Office of Food Safety, Donald W. Kraemer, Ph.D. to members of the Interstate Shellfish Sanitation Conference (ISSC), October 16, 2009). This new policy as currently described by the Agency is disturbing in both its content and means of development and implementation. We are requesting the FDA stop any plans for policy change relative to Vibrio vulnificus (V.v.) and continue working cooperatively within the ISSC towards its goal of a 60% reduction in V.v. illnesses through continued implementation of the V.v. Management Plan.

On October 17, 2009 the FDA further advised the ISSC that it intends to unilaterally change the seafood HACCP guidance document regarding V.v. This requirement would prevent traditional raw oysters from the Gulf of Mexico states from being served in the United States for over half of the year. The suggested change would force the oyster community to implement mandatory post harvesting processing, using methods such as mild heat treatment, freezing, high pressure and low-dose gamma radiation.

The Gulf Coast oyster community provides two-thirds of the nation’s oysters and has a $500 million annual economic impact. The oyster community is already one of the most regulated food groups in the United States. On average, the V.v. infection rate from the consumption of raw Gulf Coast oysters is extremely rare and does not occur in the general population. The ISSC in conjunction with the FDA and its members have worked very hard to formulate and improve plans to reduce V.v. illnesses from raw shellfish.

In 2001 the ISSC established the Vibrio vulnificus Management Plan. FDA was intimately involved in the development of this Plan. FDA also concurred at that time and on several later occasions with the adoption and implementation of illness control measures in the Plan. In May 2010 the Plan requires implementation of measures which will ensure, at a minimum, a 60% reduction in V.v. illness rates compared to a baseline rate of illness. This V.v. illness reduction plan in conjunction with the previously implemented Vibrio parahaemolyticus illness reduction plan required Gulf oyster harvesters and dealers to invest substantially in on-board refrigeration systems. In many cases, dealers and harvesters have
already invested in new on-board or dockside refrigeration or icing systems and are upgrading or replacing their existing refrigeration systems. The cost to harvesters and dealers is substantial. The new post-harvest processing the FDA plans to require renders these investments useless. If all oysters are required to be post-harvest treated, then there would be no purpose in implementing expensive and logistically challenging new time-to-refrigeration requirements currently taking place in the Gulf as per the *Vibrio vulnificus* control plan.

In the development of the Plan, the FDA provided the Gulf States with a *Vibrio vulnificus* Risk Calculator. This FDA calculator has been a useful tool allowing state shellfish regulators and oyster community members to determine the best way for their state to meet the illness reduction goals of the ISSC. This calculator would also be rendered useless should all products require post-harvest processing.

Many of the Gulf State’s shellfish regulatory agencies and oyster community members have already begun implementation of procedures and processes to further reduce *V. v.* illnesses. The ISSC fully expected the FDA to support these activities in accordance with the agreements they had made within the ISSC. Instead the FDA has proposed this unilateral action effectively banning Gulf raw oysters, abandoning their commitment to working with the cooperative framework of the ISSC. This decision is not consistent with the work that has been done by the FDA and the ISSC for more than two decades and threatens to undermine efforts to address future public health challenges. For many reasons, the Agency’s sudden policy change in this regard does not make sense.

We look forward to hearing from you regarding how we can work with the Agency to continue implementation of the original *V. v.* Management Plan.

Sincerely,

Senator Mary Landrieu  
Senator Richard Shelby  
Senator David Vitter  
Congressman Jo Bonner  
Congressman F. Allen Boyd, Jr.  

Senator Bill Nelson  
Senator Jeff Sessions  
Congressman Rodney Alexander  
Congressman Charles Boustany  
Congressman Henry E. Brown, Jr.
Congressman Anh "Joseph" Cao

Congressman Jeff Miller

Congressman Mike Rogers

Congressman Gene Taylor

Congressman Charlie Melancon

Congressman Pete Olson

Congressman Steve Scalise

Congressman Rob Wittman