Congress of the United States

Washington, DC 20515

July 31, 2003

Mr. Ken B. Moore
Executive Director
Insterstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223

Dear Mr. Moore:

On April 14, 2003, the state of California implemented an emergency regulation to prevent serious injury and death from the consumption of raw Gulf Coast oysters contaminated with the bacteria *Vibrio vulnificus*. In one week, the Interstate Shellfish Sanitation Conference (ISSC) will consider whether to sanction California for taking this step on its own. We urge the ISSC not to do so.

The key question is whether California's emergency regulation is justified to protect the public health. Over the last 15 years, more than 330 people in the United States have become seriously ill, and 174 have died, from shellfish-associated *Vibrio vulnificus*. About one-fifth of these illnesses and deaths have occurred in California.[1] The incidence of *Vibrio vulnificus* infection, which is one of the most serious hazards associated with seafood, has not significantly diminished despite educational efforts and other controls put into place by the ISSC. Moreover, the ISSC's most recent effort to reduce *Vibrio vulnificus* infections offers little guarantee of significant progress for another five years.

California's emergency regulation has broken this gridlock. The state now requires that Gulf Coast oysters harvested from April to October be treated to eliminate any detectable levels of *Vibrio vulnificus*. New evidence indicates that this simple step may have already saved lives. Each May and June for the last five years, Californians have fallen seriously ill from *Vibrio vulnificus* after eating raw Gulf Coast oysters. After the emergency regulation went into effect this year, there has not been a single infection reported in the state.

While we support the ISSC's goal of achieving uniformity in state shellfish regulation, this uniformity should not put consumers at undue risk. We urge the ISSC to revisit its own standards for Gulf Coast oysters and work with California and other states on a new national system to protect the public.

Background

Vibrio vulnificus is a bacteria that thrives in saltwater and contaminates a large percentage of Gulf Coast oysters during the summer months.[2] Consumers who eat these oysters

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[1]California Department of Health Services, *Initial Statement of Reasons on Raw Oyster Regulation* (Apr. 2, 2003) (R-33-O2-E).

[2]David W. Cook et al., *Vibrio Vulnificus and Vibrio Parahaemolyticus in U.S. Retail Shell Oysters: A National Survey from June 1998 to July 1999*, Journal of Food Production, 79–87 (2002).

can develop overwhelming bacterial infection of the bloodstream that rapidly leads to death.[3] Most of those who fall ill from *Vibrio vulnificus* have an underlying health condition, such as liver disease, that predisposes them to severe infection. In some cases, these predisposing conditions have not been diagnosed at the time of oyster consumption.[4]

In 1994, because of the risk of *Vibrio vulnificus*, the FDA proposed banning the sale of Gulf Coast oysters harvested in the summer.[5] This step was opposed by the Gulf Coast oyster industry and ultimately rejected by the ISSC. With the eventual agreement of FDA, the ISSC instead adopted standards requiring consumer education and refrigeration of oysters within a certain period of time after harvesting.[6]

These standards proved wholly inadequate to protect the public. In 1994, there were 24 cases of *Vibrio vulnificus* infections attributable to shellfish in the United States reported to FDA. By 1999, there were 34 reported cases, including 20 deaths.[7] Moreover, evidence emerged that these reported numbers may significantly underestimate the true number of illnesses.[8]

The ISSC Plan

In 2001, the ISSC adopted a new plan to address *Vibrio vulnificus* contamination of Gulf Coast oysters.[9] This approach appears to suffer from several important deficiencies, including:

- An inadequate goal. The ISSC aims to reduce illnesses caused by oyster contamination with *Vibrio vulnificus* by 60% in just four states (California, Florida, Louisiana, and

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[3]R.L. Shapiro et al., *The Role of Gulf Coast Oysters Harvested in Warmer Months in Vibrio Vulnificus Infections in the United States, 1988–1996*, Journal of Infectious Diseases, 752–9 (1998).

[4]Eric Mouzin et al., *Prevention of Vibrio Vulnificus Infections: Assessment of Regulatory Strategies*, Journal of the American Medical Association, 576–8 (Aug. 20, 1997).

[5]*Raw, Unshucked Oysters May Face Ban in Summer Months*, Chicago Tribune (July 25, 1994).

[6]*Proposed Oyster Rules Vetoed*, Los Angeles Times (Sept. 14, 1995).

[7]GAO, *Federal Oversight of Shellfish Safety Needs Improvement*, 20 (July 2001).

[8]N. Banatvala et al., *Vibrio Vulnificus Infection Reporting on Death Certificates: The Invisible Impact of an Often Fatal Infection*, Epidemiology and Infection, 221–5 (June 1997).

[9]National Shellfish Sanitation Program, Interstate Shellfish Sanitation Conference, *Vibrio Vulnificus Risk Management for Oysters* (2001).

Texas) by the year 2008. Even if this limited goal is met, consumers across the country will remain at risk.

- Few mandatory standards. The plan allows states to choose from a menu of options, starting with more consumer education, a strategy that has been shown to be insufficient.[10] There is no requirement for any post-harvest treatment of oysters or equivalent action to reduce the *Vibrio vulnificus* threat until 2007 at the earliest.

- No assurance of adequate capacity for treating oysters. The ISSC plan requires that states prepare for the possibility of treating 25% of oysters to reduce *Vibrio vulnificus* levels. States have the option of preparing to treat half of all oysters, but this is not required. As a result, the plan does not even provide for the infrastructure needed to treat all raw oysters harvested during peak summer months by 2008.

Reviewing the proposed ISSC plan just prior to its enactment in July 2001, the General Accounting Office concluded that its success would be "questionable."[11]

In comments to the California Department of Health Services, the ISSC has argued that the *Vibrio vulnificus* plan resembles the Egg Safety Action Plan, which addresses the contamination of eggs with *Salmonella enteriditis*.[12] This comparison is illustrative. Unlike the *Vibrio vulnificus* plan, the Egg Safety Action Plan aims to eliminate the targeted disease entirely and includes the establishment of multiple safety standards.[13] Moreover, California has implemented additional standards beyond the Egg Safety Action Plan's requirements.[14]

California's Emergency Regulation

The legal basis for California's action derives from the state's police power to protect the public health reserved by the U.S. Constitution. Under several state laws, including the Sherman Food, Drug, and Cosmetic Law and the California Uniform Retail Food Facilities Law, the California Department of Health Services has the authority to regulate the production, labeling, advertising and sale of foods, including raw oysters. To protect the public from a hazard that has

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[10]Eric Mouzin et al., *supra* note 4; GAO, *supra* note 7.

[11]GAO, *supra* note 7.

[12]Memorandum from Ken B. Moore, Executive Director, Interstate Shellfish Sanitation Conference, to Office of Regulations, California Department of Health Services (2003).

[13]President's Council on Food Safety, *Egg Safety, From Production to Consumption: An Action Plan to Eliminate Salmonella Enteriditis Illnesses Due to Eggs* (Dec. 10, 1999).

[14]California Health and Safety Code Sections 113996 and 113997.

killed Californians in 19 out of the past 20 years, California implemented the emergency regulation on Gulf Coast oysters.

California's action was measured. The state imposed no restrictions on Gulf Coast oysters produced from November through March and did not ban the sale of Gulf Coast oysters produced during the remaining peak months of *Vibrio vulnificus* contamination. Instead, California required that any such oysters sold be first treated with "an approved method shown to reduce the level of *V. vulnificus* to 'non-detectable.'"[15] Such measures are not technically complex, cost just pennies per oyster,[16] and are effective.[17]

The economic benefits of post-harvest treatment can be expected to justify the costs. According to FDA, each averted human infection with *Vibrio vulnificus* saves over $2 million.[18] Moreover, the reduced risk of illness will increase consumer confidence and expand the market for Gulf Coast oysters. In 2000, the Center for Economics Research at the Research Triangle Institute found post-harvest treatment would benefit oyster producers "because revenues are estimated to rise more than the increase in costs associated with the treatment technologies."[19]

Most importantly, there is now evidence that California's emergency regulation may have already saved lives. According to data we obtained from the Department of Health Services, during the months of May and June from 1998 to 2002, Californians suffered serious illness or death from *Vibrio vulnificus*-contaminated Gulf Coast oysters. Since the emergency regulation took effect in April, however, not a single case of this deadly infection in the state has been reported. As illustrated in Figure 1, California is on track to break the cycle of death and disease from contaminated oysters.

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[15]17 California Code of Regulations 13675.

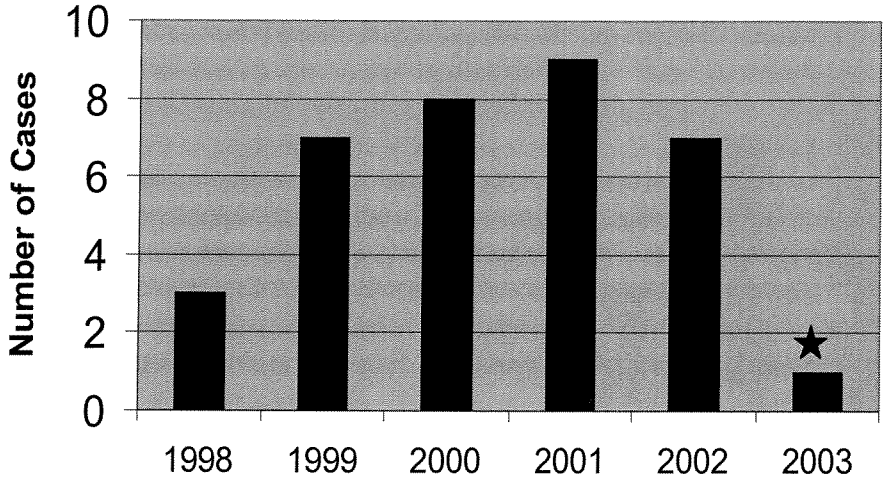
[16]Research Triangle Institute, Center for Economics Research, *Economic Impacts of Requiring Post-Harvest Treatment of Oysters* (Mar. 2000) ("the cost estimates for treatment of raw halfshell oysters range from 3.3 to 17.7 cents per oyster").

[17]*See, e.g.*, L.S. Andrews et al., *Low Temperature Pasteurization to Reduce the Risk of Vibrio Infection from Raw Shell-Stock Oysters*, Food Additives and Contaminants, 787–791 (2000).

[18]60 Federal Register 65098.

[19]Research Triangle Institute, *supra* note 16.

Figure 1: *Vibrio Vulnificus* Illnesses Associated with Raw Gulf Shellfish in California



★ No cases reported through July 21, 2003 after emergency regulation implemented on April 14, 2003.

Source: California Department of Health Services (July 21, 2003)

Conclusion

Despite this progress, California's action has generated significant opposition within the oyster industry, Gulf Coast states, and the ISSC. One important factor driving this protest is the understandable desire to maintain uniformity in the regulatory system overseen by FDA and the ISSC. If each state were to develop conflicting safety protections, the resulting array of laws could unduly hamper trade and create confusion for consumers.

While we recognize the desire for consistency across states, the answer is not to weaken the California standard but to strengthen the standard applicable in other states. The ISSC should revisit its own *Vibrio vulnificus* plan. With a clear signal from the ISSC, the Gulf Coast oyster industry could develop the capacity to treat all of its summer oysters as quickly as possible. Such a step would undoubtedly "foster and improve the sanitation of shellfish in this country," the primary objective of the ISSC.[20]

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[20]ISSC, *Constitution, By-Laws and Procedures of the Interstate Shellfish Sanitation Conference* (2003).

An action by the ISSC to undermine the California standard would be both unwise and without legal basis. It is our understanding that the ISSC is using the complaint process under Procedure IX in its bylaws to consider taking unprecedented action against California. This procedure, however, appears designed to sanction states that are not doing enough to protect the public — not those taking additional safety steps. For example, Procedure IX includes a list of sanctionable deficiencies that includes such topics as "failure to close in an emergency situation," "lack of biotoxin contingency plan," and "inadequate state laws/regulations to enforce program."[21] California's action does not fall into any of the possible categories.

At its upcoming meeting, the ISSC may consider authorizing the sanction or expulsion of states that enact public health measures. Doing so would be a step in the wrong direction, and we would urge FDA to strongly oppose any such changes.

We recognize that the ISSC performs a critical role in the U.S. food safety system. While the current dispute over Gulf Coast oyster regulation is just one part of your organization's efforts, it nonetheless presents an opportunity to take important action to protect the public. We urge the ISSC to work with California and other states to create a strategy for addressing *Vibrio vulnificus* that protects consumers across the country and in doing so enhances confidence in the shellfish industry.

Thank you for considering our views on this matter.

Sincerely,

Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
U.S. House of Representatives

Barbara Boxer
Senator
U.S. Senate

cc: Mark B. McClellan, Commissioner, Food and Drug Administration
Diana M. Bontá, Secretary, Department of Health Services

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[21] *Id.*