June 13, 2003

Office of Regulations  
Department of Health Services  
714 P Street, Room 1000  
P.O. Box 942732  
Sacramento, California 94234-7320

Re: Comment on Notice of Emergency Rulemaking: Raw Oysters  
Control Number R-33-02E

Dear Office of Regulations:

The California Department of Health Services (DHS) has adopted an emergency regulation amending the California Code of Regulations (CCR) Title 17, Section 13675, to prevent illness and deaths associated with the consumption of raw oysters contaminated with Vibrio vulnificus (V. vulnificus). Among other things, the amended regulation will restrict the sale of raw oysters harvested from the states bordering the Gulf of Mexico from April through October, unless the oysters are treated with a scientifically validated process to reduce V. vulnificus to non-detectable levels. In addition, the amended regulation requires retailers to provide a written warning, in English and Spanish, concerning the risks associated with consumption of raw Gulf oysters.

On behalf of the Center for Science in the Public Interest (CSPI), we are writing in support of the regulation since it constitutes a significant step in protecting California consumers from illnesses and deaths associated with consumption of raw Gulf oysters contaminated with V. vulnificus. The emergency regulations are necessary because federal regulators and the industry-dominated cooperative program have failed to implement strong measures to address this public-health crisis. Indeed, given the severity of the illness caused by this dangerous pathogen, CSPI urges California DHS to consider limiting the sale of raw Gulf oysters during the entire year, not just the warm weather months, unless they have been processed to reduce V. vulnificus to non-detectable levels.

CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its Nutrition Action Healthletter. Of these subscribers, over 94,000 reside in California. CSPI also is the publisher of Outbreak Alert!, an annual listing of foodborne-illness outbreaks throughout the country, including those from V. vulnificus. We also have been members of the Interstate Shellfish Sanitation Conference (ISSC) for many years and have attended several ISSC meetings at which shellfish safety standards were deliberated.
1. *V. vulnificus Infections Associated With Consumption of Raw Gulf Oysters Continue to Sicken and Kill People*

*V. vulnificus* is a bacterium that naturally occurs in seawater and thrives at warm temperatures. It is present in virtually all shellfish harvested from the Gulf of Mexico during the warmer months.¹ *V. vulnificus* infections are acquired primarily through consumption of contaminated raw or undercooked shellfish, particularly oysters. Although *V. vulnificus* can sicken healthy people, persons particularly at risk are those with pre-existing liver disease, diabetes, certain blood disorders, or compromised immune systems. In such persons, the organism can infect the bloodstream, causing primary septicemia, which is fatal in 50% of the cases.²

Of non-cholera *Vibrio* infections reported to the Centers for Disease Control and Prevention (CDC), *V. vulnificus* accounts for the greatest proportion of reported deaths, with a case-fatality rate exceeding 50%. On a national level, between 1989 and 2002, there were a reported 325 individual illnesses from *V. vulnificus*, causing 169 deaths, from consumption of raw or lightly cooked shellfish.³ According to the California DHS, between 1989 through 2002, there have been 60 illnesses resulting in 37 deaths associated with consumption of raw oysters containing *V. vulnificus*.⁴ As long as raw oysters harvested from Gulf waters are contaminated with *V. vulnificus* and continue to sicken and kill Californians, as well as other Americans, the sale of untreated raw oysters should be banned.

2. *Consumer Education and Regulatory Efforts Have Failed to Protect Individuals from V. vulnificus-Related Illness and Death*

The current national regulatory system does little or nothing to prevent contaminated raw shellfish from reaching large numbers of consumers. Although the Food and Drug Administration (FDA) adopted the Hazard Analysis and Critical Control Point (HACCP) system for seafood in 1995, the seafood HACCP has done little to protect consumers against the dangers

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³ Food and Drug Administration, Center for Food Safety & Applied Nutrition, Shellfish-Related *Vibrio vulnificus* Cases/Deaths, obtained by Freedom of Information Act (FOIA) request [hereinafter FDA, Shellfish-Related *Vibrio vulnificus* Cases/Deaths]. According to the Centers for Disease Control and Prevention, *V. vulnificus* is a rare cause of disease, but it is also under-reported. See CDC, *Vibrio vulnificus*.

of *V. vulnificus*. Since the rule was implemented in 1997, at least 85 people have died and 71 others have become ill as a result of eating raw shellfish harboring *Vibrio vulnificus*.\(^5\) Those figures show no improvement over those from the years prior to HACCP implementation,\(^6\) and attest to the rule’s inability to ensure seafood safety.

The major reason for HACCP’s failure to control *Vibrio vulnificus* is that the seafood HACCP rule contains no pathogen-reduction performance standards.\(^7\) Though the FDA directs shellfish processors to ensure that their HACCP plans comply with the post-harvest refrigeration requirements in the National Shellfish Sanitation Program Manual of Operations (NSSP Manual), the existing refrigeration standards have been weakened due to the influence of the shellfish industry and state regulators from shellfish-producing states.\(^8\) Furthermore, as the California DHS has recognized, refrigeration may not prevent illness because infectious levels of *V. vulnificus* can already be present at the time of harvest.\(^9\) Only post-harvest treatment methods such as mild pasteurization and hydrostatic pressurization are consistently capable of reducing *V. vulnificus* in oysters to a non-detectable level. However, those methods are not required under the seafood HACCP rule.\(^10\)

Because of stiff resistance from much of the shellfish industry to regulatory solutions for the control of *V. vulnificus*, the primary national strategy adopted by the FDA and the Interstate Shellfish Sanitation Conference (ISSC), has been to focus on consumer education concerning the dangers of consumption of raw Gulf oysters.\(^11\) California officials, consistent with the policies of the ISSC and FDA, has for many years conducted consumer education campaigns to prevent *V. vulnificus* deaths and illnesses. Those campaigns have continued into this year and are funded by

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\(^7\)Though source tagging is mandated under existing HACCP regulations, that requirement cannot guarantee that all incoming oysters will be free of harmful levels of *Vibrio vulnificus*. The tagging requirements are part of FDA’s seafood HACCP regulations, and are codified at 21 C.F.R. §§ 123.28 and 1240.60.

\(^8\)FDA does not unilaterally promulgate the regulations contained in the NSSP Manual, but instead acts in partnership, through the Interstate Shellfish Sanitation Conference (ISSC), with state regulators and industry in developing the regulations. States that participate in the NSSP routinely adopt those regulations as state law or regulations, but the contents of the NSSP Manual are not themselves enforceable by federal or state authorities.


\(^10\)CSPI petitioned the FDA to establish a performance standard of nondetect for *V. vulnificus* in 1998; however, the FDA denied the petition in 2001.

\(^11\)Safety standards for shellfish are established by the Interstate Shellfish Sanitation Conference (ISSC), an organization consisting of shellfish industry representatives and state regulators, with participation by the FDA, and set forth in the Shellfish Model Ordinance. The Model Ordinance provisions may only be adopted, altered, or eliminated by means of the formal ISSC process. However, the FDA has allowed the ISSC to establish what amounts to an industry “vetting” process for all proposed changes to shellfish-safety standards. *See CSPI, Death on the Half Shell* (June 2001), at pp. 9-12.
California taxpayer dollars, as the state does not have statutory budget authority to accept federal funding for this purpose. Moreover, to accept ISSC funding for consumer education campaigns would be to invite a conflict of interest, since the regulated industry has significant decision-making authority in the ISSC. More importantly, as the California DHS has noted, “[e]ven if extensive educational resources were available, success would still be unlikely because many at-risk persons do not know, or deny, they are at risk.”12 CSPI strongly agrees.

In July 2001, the ISSC approved a plan, Issue 00-201, that would retain education as the primary national strategy. The ISSC’s *V. vulnificus* control plan would not require post-harvest treatments of Gulf shellfish for many years and then only if the educational activities do not reduce the current rate of *V. vulnificus* illnesses by 60%. Under the plan, an illness reduction of 40% must be met by 2005-2006. However, harvest controls would be required only if an illness reduction of 60% is not attained by 2007-2008. Moreover, the plan is intended to promote consumer education and prevention measures as a means “to avoid regulatory actions which would significantly affect the shellfish industry” – not as a means to protect the public health.13

In the face of industry’s continued unwillingness to adopt more rigid controls on raw oysters harvested from Gulf waters and FDA’s failure to adopt a performance standard mandating that shellfish processors achieve nondetectable levels of *V. vulnificus*, it is necessary for California to act to protect its own consumers. Waiting another five years to add these protections is simply too long. The past decade’s mounting toll of deaths and illnesses caused by raw Gulf Coast oysters contaminated with *Vibrio vulnificus* tragically demonstrate that the existing consumer education approach does not work.

3. **The Potential Benefits of the California Regulation Far Outweigh Its Potential Costs**

Prohibiting the sale of untreated raw oysters would produce enormous benefits for California, both economic and non-economic. Among other things, the ban would:

- significantly reduce, and possibly eliminate, the huge economic costs, and the immeasurable emotional toll of *Vibrio vulnificus* deaths and illnesses;

- further enhance raw shellfish safety by producing a reduction in the levels of other harmful *Vibrio* species, including *Vibrio parahaemolyticus* and *Vibrio cholerae* non-01; and

- reduce the liability risks faced by harvesters, processors, and retailers of shellfish from waters contaminated with *Vibrio vulnificus*, and avert needless litigation.

In assessing the economic impact of its seafood HACCP rule, FDA estimated the


approximate societal cost of deaths and illnesses due to *Vibrio vulnificus* infection from consuming raw shellfish. Specifically, FDA estimated that each case of *Vibrio vulnificus* infection costs the economy $2 million, that there are approximately 60 cases each year, thus averting all 60 cases of *Vibrio vulnificus* would save approximately $120 million annually.\(^{14}\)

The $120 million figure actually understates the probable economic benefit since FDA used a rather conservative estimate for the societal cost of each infection. FDA opted to assign a cost of $2 million to each generic infection, regardless of whether or not it leads to the victim’s death. A more accurate analysis would instead assign the full value of a human life to those cases where the *Vibrio vulnificus* infection is fatal, and a lower value to those cases in which the victim survives. Such an analysis would proceed as follows. FDA estimates that there are approximately 60 cases per year of *Vibrio vulnificus* infection. As set forth above, epidemiological data show that about 50 percent of all reported infections lead to the death of the victim. Therefore, each year brings approximately 30 cases of fatal infection and 30 cases of non-fatal infection. To ascertain the cost to society of the fatal cases, one must estimate the value of a human life. FDA put that value at approximately $5 million in its evaluation of the economic impact of the seafood HACCP rule.\(^{15}\) Therefore, the savings to society, in economic terms would be $150 million per year (30 cases x $5 million per case).

There would be additional savings from averted deaths (non-fatal cases). Estimating the value of those cases is difficult; however, the average cost of each non-fatal illness is likely to be relatively high because survivors of *Vibrio vulnificus* infections often suffer amputation or other severely debilitating injuries that require long-term care, all at significant cost to the health care system.

The ban on the sale of oysters during warm weather months could also have another benefit – reducing contamination of oysters with other *Vibrio* species. Numerous species of *Vibrio* bacteria other than *Vibrio vulnificus* are prevalent in raw shellfish sold in the United States. Some of those species, most notably *Vibrio parahaemolyticus* and *Vibrio cholera* non-01, cause a significant amount of foodborne illness in this country. In the preamble to the seafood HACCP rule, FDA estimated that about 1,000 people are sickened by non-*vulnificus* *Vibrio* species each year, at an overall cost of approximately $3 million.\(^{16}\) As a result of California’s ban on untreated oysters during warm weather months, some processors are likely to adopt post-harvest treatment technology to eliminate *Vibrio vulnificus*. These same treatment technologies may also be useful in reducing the contamination of raw molluscan shellfish by other *Vibrio* species that cause foodborne illness.


\(^{16}\) *Seafood HACCP, Final Rule*, p 0 Fed. Reg. at 65,185-86.
Avoidance of costly litigation should also be considered in assessing the benefits of the emergency rule. Consumers have shown a willingness to bring lawsuits when they or their loved ones are sickened or killed by contaminated shellfish. On a national level, since 1989, at least six product-liability lawsuits have been brought in the United States.\(^{17}\) Retailers as well as companies at every stage of the distribution channel risk product-liability lawsuits, and their potentially huge monetary judgments. Even government regulatory agencies face the specter of potential litigation over their alleged failure to protect consumers from unsafe raw-shellfish products.\(^{18}\) In California, as the California DHS has noted, insurance settlements for two cases were $516,000 and 1.3 million.\(^{19}\)

Regardless of the outcome of such cases, there is no doubt that litigation over injuries caused by raw shellfish contaminated with *Vibrio vulnificus* could become a tremendous drain on both societal and industry resources. Like the other unnecessary costs associated with the sale of unsafe raw shellfish, the costs of litigation would be averted if the California ban is maintained and *Vibrio vulnificus*-contaminated oysters are kept off the market.

Whatever the costs estimated by the shellfish industry of treating their oysters for sale in California, there is no reason to believe that the increased costs would be borne by the shellfish industry alone. Instead, a substantial portion, if not all, of the post-harvest costs would be passed on to consumers in the form of slightly higher prices. However, the selling prices of Gulf Coast shellfish are typically lower than those of cold-water shellfish, so the additional cost attributable to treatment would likely only bring Gulf Coast shellfish prices in line with the selling prices of oysters from other regions. Even if the price of treated Gulf Coast oysters were to exceed the price of those other oysters, there has been changing price elasticity for Gulf Coast oysters over the last two decades. Thus, there is little reason to believe that the anticipated increase in retail price would dissuade large numbers of consumers from purchasing treated Gulf Coast oysters. Moreover, elimination of *Vibrio vulnificus* from Gulf Coast raw oysters could actually stimulate demand for oysters in California by expanding the market to include those who have chosen not to consume raw oysters because of safety concerns.


\(^{18}\) The Louisiana Department of Health and Human Resources was named as a defendant in both Simeon and Winstead, *supra*, and its successor agency, the Louisiana Department of health and Hospitals was named in Gregor and Grayson, *supra*.

\(^{19}\) *Initial Statement of Reasons*, at p. 2.
4. **Arguments To Rescind the California Regulation Are Not Compelling.**

At the June 11, 2003 hearing on the California regulations, some witnesses called on California officials to lift the ban on raw, untreated Gulf oysters. However, those arguments failed to justify a rescission of California’s oyster regulation, for the following reasons:

- **This is a public-health crisis which needs an emergency response from public-health officials.** The CDC recently reported that from 1996-2002, the estimated incidence of *Vibrio* infections increased 126%.\(^20\) Though these data include illnesses from all *Vibrio* bacteria, among this family of bacteria, *V. vulnificus* is the most deadly.

- **California officials have worked with the ISSC and FDA for years in trying to resolve this problem. California’s regulations were issued after the years of inaction and delay by the ISSC and FDA.** As far back as 1990, California officials asked the ISSC and FDA to consider banning sales of Gulf shellfish harvested during warmer months, because consumer education campaigns had been unsuccessful. The 2003 ban was issued only because, as outlined above, the post-harvest treatment requirements in the ISSC’s plan won’t go into effect for several years. Meanwhile, needless deaths and illnesses will continue.

- **There is no ambiguity in the wording of the regulations.** Both the ISSC control plan and the California regulations are based on the sale of treated oysters for “raw” consumption. Some have argued that there are textural differences in treated oysters, but that does not change their status under the ISSC and California measures.

- **Mississippi has had two *V. vulnificus* illnesses linked to shellfish harvested from Mississippi waters. Therefore, the state is not being unfairly burdened by the California regulations.** Government data show that in June 1998, raw oysters harvested in Mississippi’s Pass Christian Reef sickened a consumer in Florida. In November 1998, lightly steamed oysters from the same area sickened a consumer in North Carolina.\(^21\)

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Conclusion

Public health considerations – not industry concerns – must guide the decisions of California regulators when it comes to protecting California consumers from the dangers of consumption of raw untreated Gulf oysters during warm weather months. In the past, the Gulf Coast shellfish industry has wielded its power within the ISSC to squash any efforts at meaningful reform, even efforts initiated by the FDA. Limiting the sale of untreated Gulf-harvested oysters during warm weather months gives processors of raw shellfish a strong incentive to take advantage of the new technologies capable of eliminating *V. vulnificus* from their products. California should not allow industry interests to alter the strong step taken by the Department of Health Services.

Respectfully submitted,

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