

**INITIAL STATEMENT OF REASONS
FOR
PROPOSED RAW OYSTERS REGULATIONS
OF THE
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH**

**REGARDING THE CALIFORNIA CODE OF REGULATIONS, TITLE 17, DIVISION 1,
CHAPTER 5, SUBCHAPTER 2, GROUP 1, ARTICLE 10.5**

The Administrative Procedure Act (APA) requires that an Initial Statement of Reasons be available to the public upon request when rulemaking action is being undertaken. The following information required by the APA pertains to this particular rulemaking action.

SUMMARY OF THE PROPOSED REGULATIONS:

The California Department of Public Health (Department) is authorized to adopt and enforce regulations pursuant to California Health and Safety (HSC) Code Section 131200, for the execution of its duties. The Department is also specifically authorized to establish and enforce regulations pertaining to certain health and safety concerns associated with raw Gulf of Mexico (Gulf) oysters in California pursuant to HSC Sections: 109875, 110105, 112150 and 113700.

The purpose of this rulemaking action is to harmonize California's molluscan shellfish regulations with the provisions adopted for the National Shellfish Sanitation Program (NSSP)¹ by the U.S. Food and Drug Administration (the FDA) and Interstate Shellfish Sanitation Conference (ISSC).² With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for the bacterium, *Vibrio Vulnificus* (*V. vulnificus*), in post-harvest processed oysters.

These proposed regulatory amendments will likely result in the removal of sanctions against California by ISSC and avert the negative economic impact to California businesses that may result from additional administrative actions directed at California by ISSC and the FDA. In addition, the amendments provide the Department with the authority to uniformly regulate raw oysters processed to less than 30 MPN/g, but harvested during different times of the year, while maintaining the current level of restriction on the sale of raw³ Gulf oysters harvested from the states of Alabama, Florida, Louisiana, Mississippi, or Texas during April through October. Additional benefits anticipated by the Department include a reduction of costs associated with processing oysters using certain technologies and an increase in the amounts and varieties of post-harvest processed oysters imported into California to the benefit of consumers.

¹ The NSSP was developed to assist in the control of disease associated with the consumption of raw shellfish. The Public health control procedures established by the NSSP are supported by the FDA and dependent on the cooperative efforts of state regulatory agencies and the shellfish industry.

² The ISSC is one of three FDA cooperative programs (shellfish, milk, and retail food) established to promote food safety. The ISSC is composed of the FDA, state regulatory agencies including California, and the shellfish industry.

³ When originally promulgated, CCR Section 13675 was directed at reducing the illness from the consumption of raw oysters that had not been processed to reduce pathogens such as *V. vulnificus*. Post-harvest processed oysters are regulated as raw, but have been subjected to a process to reduce levels of targeted *V. vulnificus*.

The proposed regulatory amendments are consistent with the findings of the “Risk Assessment of *Vibrio vulnificus* in Raw Oysters” conducted by the Food and Agriculture Organization of the World Health Organization (FAO/WHO). The findings are also supported by epidemiological data maintained by the FDA. Since becoming commercially available in 2005, there have been no epidemiologically-linked *V. vulnificus* infections associated with raw oysters processed at the less than 30 MPN/g level documented by the FDA.

This particular rulemaking action implements, interprets, and makes specific the California health and safety statutes that provide consumer warnings about the risks associated with the consumption of Gulf oysters that may contain the bacterium *V. vulnificus*, and the sales restrictions, warning exemptions, and procedural verifications for post-harvest processed Gulf oysters processed to reduce *V. vulnificus*. The purpose of this proposal is to specifically amend Title 17, of the California Code of Regulations (CCR) Sections 13675 and 13676. The proposed amendment to subsection 13675(a)(8) revises the microbiological level for *V. vulnificus* in post-harvest processed Gulf oysters from the current level of less than 3 Most Probable Number per gram (MPN/g) to less than 30 MPN/g. This regulatory amendment will require that the less than 30 MPN/g microbiological level of *V. vulnificus* is met through a performance standard that achieves a minimum 3.52 log reduction. Additionally, the proposed amendment to subsection 13675(a)(8) revises the laboratory procedures employed for the detection and enumeration of *V. vulnificus* in post-harvest processed oysters to be consistent with the revised microbiological level. The proposed amendments to CCR Section 13676 make subsection 13676(a)(4) consistent with the amendments to CCR Section 13675.

AUTHORITY AND REFERENCE CITATIONS:

This rulemaking action implements, interprets, and makes specific the California statutes associated with providing consumer warnings about the risks associated with consumption of Gulf oysters that may contain the bacterium *V. vulnificus* and sales restrictions, warning exemptions, and procedural verifications for raw Gulf oysters processed to reduce *V. vulnificus*. The statutory authorities cited for this regulatory proposal are found in Health and Safety Code Sections 110065, 110105, 110430, 112165, 113707, 131050, 131051, 131052, 131055, 131056, and 131200. The references cited in this regulatory proposal are Health and Safety Code Sections 110175, 110435, 110545, 110560, 110565, 110660, 110705, 112165(c), 112195, 112200, 113980, 114029, 114039, 114039.1, 114039.2, 114039.3, 114039.4, and 131071.

BACKGROUND AND POLICY STATEMENT OVERVIEW OF SANITARY CONTROL OF SHELLFISH:

Molluscan shellfish such as oysters, clams, mussels and scallops may be found in a variety of market forms. These may include raw, live; raw, fresh (not live); or cooked, including smoked. The shellfish may be in-the-shell, on-the-half-shell, or removed from the shell (shucked) and stored refrigerated or frozen.

Public Health Concerns Associated with Foodborne Exposure to *V. vulnificus*

Epidemiological studies have demonstrated that human illness can result from *V. vulnificus* through the consumption of contaminated seafood.⁴ “Healthy” individuals are at low-risk of foodborne infection from *V. vulnificus*. However, ingestion of *V. vulnificus* by individuals considered at “high-risk” may result in systemic infections, leading to serious illness or death. Persons considered “high-risk” include those with pre-existing chronic illnesses or those with compromised immune systems. Major risk factors include chronic liver diseases, including cirrhosis from alcohol consumption, diabetes, cancer, HIV/AIDS, hemochromatosis, chronic kidney disease, and decreased resistance from the use of immunosuppressive drugs or steroids. The FDA estimates that 7% to 16% of the U.S. population has conditions that place them at “high risk” for serious infection.

On average, approximately 32 primary foodborne *V. vulnificus* septicemia cases are reported annually in the United States. During the period 2000 through 2010, ISSC reported 348 illnesses linked to oysters containing *V. vulnificus*. These infections are of concern to public health agencies because of the severity of their outcome. Foodborne *V. vulnificus* infections have a mortality rate of approximately 50%. This represents the highest case fatality rate of any foodborne disease agent. Moreover, virtually all foodborne *V. vulnificus* infections have been associated with the consumption of raw oysters harvested from the Gulf. Nationally, the majority of reported *V. vulnificus* cases occur during the warmer months when levels of the pathogen are highest in Gulf waters and Gulf oysters.

Public health controls have been a challenge for regulatory agencies because *V. vulnificus* bacteria are naturally present in marine environments. These bacteria do not alter the appearance, taste or odor of oysters, and they are not detected by traditional indicators of shellfish safety (e.g. shellfish contaminated with sewage, pollution, etc.). Furthermore, *V. vulnificus* concentrations can vary from different geographical locations or between individual oysters harvested at the same time from the same growing waters. Nonetheless, studies have consistently demonstrated a strong association between the levels of the bacterium and water temperature. Within the U.S., levels of *V. vulnificus* are among their highest in waters and oysters of the Gulf of Mexico during the warmer months of the year. These levels correlate closely to the peak in reported illnesses during April through November.

Public Health Concerns in California

Illnesses and deaths associated with *V. vulnificus* in raw Gulf oysters have long been identified as a significant public health concern within California. CCR Section 13675 was adopted in 1991 to augment general food laws and address the specific concerns associated with *V. vulnificus* in raw Gulf oysters. The regulation requires retail food facilities in California to provide a written warning to consumers, specifically high-risk individuals, concerning the potential dangers associated with consuming raw Gulf

⁴ Exposure to *V. vulnificus* through wounds can also be a source of serious infection.

oysters. Section 13675 specifies the wording and manner in which warnings are displayed and the information that must be present on containers of raw Gulf oysters. Revisions were made in 1997 that required retail facilities to post oyster warnings in Spanish, as well as English, and mandated greater prominence of the warnings. The revisions also gave the Department authority to grant exemptions from the warnings, if the oysters were processed with a validated treatment process to reduce levels of *V. vulnificus* to less than 3 MPN/g.

In spite of educational and regulatory efforts undertaken by the Department, California continued to experience *V. vulnificus* illnesses and deaths from raw Gulf oysters. In April 2003, the Department adopted emergency amendments to CCR Section 13675 that annually restricted the sale of raw Gulf oysters harvested from April 1 through October 31, unless processed to reduce levels of *V. vulnificus* to less than 3 MPN/g.

Overview of Regulatory Controls of Shellfish Sanitation in California

Within California, raw oysters whether live, fresh, or frozen are regulated by California's general food laws specific to the harvesting, processing, and distribution of oysters.

The Sanitary Control of Shellfish Law found at HSC Section 112150 et seq. sets safety, labeling, and other standards for shellfish handling and processing in California. Pursuant to these provisions, the Department is authorized to conduct surveys of shellfish growing waters to ensure shellfish grown in the water are safe as an article of food and meet bacteriological, chemical, and toxicological standards. The Department also issues shellfish growing certificates; issues licenses to dealers who process, hold, and distribute shellfish; and regularly inspects shellfish dealers for compliance with applicable requirements.

The Sherman Food, Drug, and Cosmetic Law found at HSC Section 109875 et seq. provides labeling, misbranding, and adulteration provisions for regulating food for human consumption, including shellfish.

CCR Section 13675 provides detailed requirements for handling shellfish and specific provisions for raw Gulf oysters. Provisions include requirements for point-of-sale warnings and sales restrictions on raw Gulf oysters harvested during April through October. CCR Section 13675 contains exemptions from warnings and sales restrictions if oysters have been processed to reduce the level of *V. vulnificus* to less than 3 MPN/g. CCR Section 13676 contains procedures for verifications of oyster treatment processes that exempt dealers and retailers from the warning and sale provisions. The California Retail Food Code (CRFC) found at HSC Section 113700 et seq. sets safety, labeling, and other standards for all food, including shellfish, sold at retail in California by restaurants, markets, and other retail food facilities.

California has also adopted certain federal standards associated with foods including oysters through HSC Section 110105. Title 21, Code of Federal Regulations (CFR), Part 110 sets minimum standards for sanitation and production controls in food processing facilities, including shellfish processors. Title 21, CFR, Part 123, the Hazard

Analysis Critical Control Point (HACCP) regulation requires all seafood processors, including shellfish processors, to develop formal food safety systems known as HACCP plans to address identified seafood safety concerns. The HACCP regulation also establishes requirements for maintaining records of sanitation controls and conditions within seafood facilities.

In California, the Department is responsible for enforcing the provisions of the HSC and regulations governing the sanitary control of shellfish. The Department is also the lead agency responsible for ensuring that local health departments in California effectively and uniformly enforce the CRFC. The major purposes of these laws are to ensure the safety of California's food supply and to protect the public from avoidable food safety risks, including illnesses and deaths. The Department carries out its responsibility in part by adopting and amending regulations to implement, interpret, and make specific the requirements of these laws.

Sanitary Control of Shellfish in the United States

Nationally, the safety of food is regulated by the FDA under provisions of the federal Food, Drug, and Cosmetic Act and Public Health Services Act. These laws empower the FDA with oversight of food, but they do not provide the agency with direct authority over molluscan shellfish dealers that are regulated by state regulatory authorities. As such, the FDA determined the most effective way to assure the safety of shellfish sold in interstate commerce was to establish a coordinated program in support of state shellfish laws under a national shellfish program.

The National Shellfish Sanitation Program (NSSP)

The NSSP was established by the Surgeon General of the Public Health Service in 1925. The program was developed in response to local and state regulatory agency concerns about the spread of illnesses associated with the consumption of molluscan shellfish received through interstate commerce.

The NSSP is a voluntary, cooperative organization created as a mechanism for regulatory agencies and other interested parties to develop uniform control guidelines to assure the safety of molluscan shellfish. Within the NSSP, state regulatory agencies and the federal government have specific roles for assuring the safety of shellfish. States have the primary responsibility for: 1) issuing certificates for shellfish dealers that meet accepted, uniform standards; 2) approving and monitoring shellfish growing areas; and 3) inspecting shellfish processing and distribution plants. The FDA supports state efforts by providing technical support; publishing the Interstate Certified Shellfish Shippers List (ICSSL) of shellfish shippers that are deemed by the state to be in compliance with shellfish sanitation standards; conducting scientific investigations; and serving as a repository for information concerning shellfish safety.

In 1968, the responsibility for administering the NSSP was transferred to the Commissioner of Food and Drugs, within the FDA. During this time, the FDA proposed the enactment of national shellfish regulations, but ultimately it concluded that uniform

national controls would best be achieved by encouraging the establishment of uniform standards adopted by the states through the NSSP. Although California's shellfish industry is regulated by provisions contained in the HSC and CCR, the FDA regularly audits the California shellfish program for compliance with the standards of the NSSP.

Interstate Shellfish Sanitation Conference (ISSC)

In 1982, ISSC was established to assist in the development of guidelines to assure the safety of shellfish for adoption into the NSSP.

ISSC is comprised of representatives from the FDA and other federal regulatory agencies, states, researchers, laboratory specialists, statisticians, epidemiologists, marine resource experts, and the shellfish industry. Foreign governments also participate in ISSC and adopt the provisions of the NSSP under international agreements with the FDA.

In 1984, the FDA entered into a Memorandum of Understanding (MOU) with ISSC. The MOU gave ISSC the responsibility for maintaining the cooperative relationship between the FDA, states, and industry. Under ISSC, procedures have been established for state agencies to develop minimum standards to assure the sanitary control of shellfish. These guidelines are maintained and updated by ISSC and presented to the FDA for formal concurrence prior to adoption into the NSSP *National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, Model Ordinance* (NSSP Guide).

The NSSP Guide serves as a model for member states to adopt shellfish safety provisions into law or regulation. This also provides the FDA with a mechanism to evaluate the equivalency of state and foreign shellfish control programs. Member states and foreign governments of the ISSC, including California, agree to the principles of uniformity by adapting their regulatory requirements to the NSSP Guide. In addition, ISSC members formally agree to adhere to the protocols and procedures of the ISSC Constitution. State and national shellfish authorities in compliance with the provisions of NSSP are authorized by the FDA to approve shellfish dealers for listing in the ICSSL. Under the NSSP, interstate shipments of shellfish are only authorized for firms listed on the ICSSL. Therefore, shellfish products received from sources other than those listed on the ICSSL are subject to regulatory action by shellfish authorities of the receiving state.

CHANGES IN LABORATORY METHODS AND REGULATORY STANDARDS: *ISSC and FDA Research Activities*

ISSC has deliberated on the public health impacts of *V. vulnificus* in raw Gulf oysters for many years. *V. vulnificus* intervention activities have traditionally focused on educational programs directed at high-risk consumers. Efforts have also been directed at time-temperature control measures for harvested oysters and the potential imposition of post-harvest processing during certain times of the year. Concurrent with these efforts, the shellfish industry has applied new and updated food processing technologies including cryogenic-quick freezing, mild heat treatment, high-pressure, and irradiation to

reduce the public health impact of *V. vulnificus*. Each of these production methods has been shown to effectively reduce the levels of *Vibrio* species in oysters.

In support of this effort, the FDA and ISSC assisted in the development of national shellfish safety goals and protocols. In 2001, ISSC adopted a formal *V. vulnificus* Management Plan (Vv Management Plan) focused on reducing the number of *V. vulnificus* illnesses in the United States. Within ISSC, the *Vibrio* Management Committee (VMC)⁵ was established to develop and evaluate programs for the Vv Management Plan. In addition, the VMC became a national, technical resource on issues related to *Vibrio* information including post-harvest processed *V. vulnificus* illness reporting, market and shelf-life studies, and other *Vibrio* related activities.

The FAO/WHO V. vulnificus Risk Assessment

In 2001, FAO/WHO initiated a *V. vulnificus* Risk Assessment (Vv Risk Assessment). The Vv Risk Assessment was conducted to quantify the health impact associated with the consumption of raw oysters containing *V. vulnificus* and to investigate the benefits of processing oysters at “targeted mitigation” levels. Although the study was conducted by FAO/WHO, an international agency, the researchers utilized the available research associated with the ecology and epidemiology of *V. vulnificus* associated with the consumption of raw Gulf oysters within the United States.

The Vv Risk Assessment evaluated a variety of data, including: total *V. vulnificus* levels at harvest; total time to harvest; *V. vulnificus* growth rates; *V. vulnificus* survival after harvest and refrigeration; the number of “high-risk” individuals in the U.S.; consumption patterns of “high-risk” populations; concentration of *V. vulnificus* at consumption; and the number of oysters consumed per serving. Statistical models were applied to these data to estimate the annual number of illnesses in the U.S. in individuals considered at highest risk that consume raw oysters containing *V. vulnificus*. The Vv Risk Assessment determined the total number of predicted illnesses for high-risk individuals consuming oysters treated to less than 3 MPN/g, less than 30 MPN/g, and less than 300 MPN/g levels was 0.16 cases per year (one *V. vulnificus* case per 10 million meals), 1.2 cases/year (8 per 10 million meals), and 7.7 cases/year (5 per 1 million meals), respectively (Table 1).⁶ The 2009 NSSP Guide states, “A WHO/FAO (2005) risk assessment indicated that a *V. vulnificus* concentration of below 30 per gram is a negligible health risk”. This determination is supported by epidemiological data maintained by the FDA. Since becoming commercially available in 2005, there have been no epidemiologically-linked *V. vulnificus* infections associated with oysters processed at the less than 30 MPN/g level documented by the FDA in “Shellfish-Related *Vibrio vulnificus* Cases/Deaths” reports.

⁵ Under the VMC, various subcommittees and workgroups were established to focus on specific components of ISSC activities directed at *V. vulnificus* monitoring and interventions.

⁶ FAO/WHO also considered pooled data sets from other research. However, the determinations of the Vv Risk Assessment were based on data consistent with *V. vulnificus* per gram typically available to consumers.

Table 1. Predicted mean and 90% confidence intervals for risk per serving and annual number of illnesses for three alternative process target levels based on Food and Agriculture Organization of the World Health Organization risk assessment of *V. vulnificus* in raw oysters.

Target <i>V. vulnificus</i> /g	Mean risk per serving ⁷	Annual number of cases
3 MPN/g	1.09 x 10 ⁻⁷ (4.10 x 10 ⁻⁸ , 2.73 x 10 ⁻⁷)	0.16 (0.06, 0.4)
30 MPN/g	8.20 x 10 ⁻⁷ (3.42 x 10 ⁻⁷ , 2.12 x 10 ⁻⁶)	1.2 (0.5, 3.1)
300 MPN/g	5.26 x 10 ⁻⁶ (2.60 x 10 ⁻⁶ , 1.05 x 10 ⁻⁶)	7.7 (3.8, 15.3)

Revisions in Post-Harvest Processing Standards

During the mid-1990s, ISSC adopted a less than 3 MPN/g microbiological level for *V. vulnificus* in post-harvest processed oysters. The less than 3 MPN/g level was the established level of detection (defined then as “non-detectable”) for the laboratory method used to enumerate *V. vulnificus*. In the absence of a scientifically-based, formal risk assessment, the less than 3 MPN/g level was deemed the most acceptable microbiological level for public safety available at that time.

Shellfish dealers utilizing approved post-harvest processes⁸ to achieve the less than 3 MPN/g level were authorized by the FDA to provide labeling declarations on oyster products indicating the shellfish was processed to reduce the target pathogen (i.e., *V. vulnificus* or *V. parahaemolyticus*) to “non-detectable levels”. In 2002, the “Post-Harvest Treatment Validation/Verification Working Group” (Work Group) was initiated under the Vibrio Management Committee of ISSC. The Work Group consisted of state agencies, the FDA, technical experts, and industry representatives. The Work Group provided Interim Guidance on validating post-harvest processing for *Vibrio* species including: the number of product samples needed to assure the process is capable of achieving the less than 3 MPN/g level; the initial levels of the target pathogen required to demonstrate the reduction to less than 3 MPN/g; and a description of the laboratory and analytical methods approved for the detection and enumeration of *V. vulnificus*.

In 2003, ISSC conducted discussions focused on revising the levels of *V. vulnificus* in post-harvest processed products associated with label declarations for enhanced safety. In a report by the Work Group of the Vibrio Management Committee, FDA representatives presented the preliminary determinations of the Vv Risk Assessment conducted by FAO/WHO.⁹ The Work Group concluded, “These findings indicated that a

⁷ FAO/WHO estimated a mean serving size of approximately 196 grams or 13.7 oysters per meal.

⁸ Process validations were submitted to FDA or state regulatory agencies for approval.

⁹ FAO/WHO published their final Vv Risk Assessment in 2005. The FDA participated in both the Risk Assessment

non-detect level of 30 MPN *V. vulnificus* for labeling claim purposes was suggested based upon the FAO-WHO risk assessment.” Based on the findings of FAO/WHO, ISSC adopted the less than 30 MPN/g microbiological level for post-harvest processed shellfish products and identified the FDA approved laboratory methods for the detection and enumeration of *V. vulnificus* commensurate with the less than 30 MPN/g level. The FDA concurred with these revisions. Each of these revisions was subsequently incorporated in the 2003 NSSP Guide. In addition, the *Validation/Verification Interim Guidance* was revised to reflect the *V. vulnificus* end-point of less than 30 MPN/g.

The NSSP Guide also contained post-harvest processing validation protocols for *V. vulnificus* established by ISSC and approved by the FDA. Validation guidance provided by ISSC includes provisions for process validation, equipment validation, re-validation, initial load testing, and verification. Since the level of *V. vulnificus* in oysters is variable, the NSSP Guide validation procedures for *V. vulnificus* specifically require dealers to demonstrate a reduction from a “worse-case” level of 100,000 MPN/g. Processing methods, capable of reducing *V. vulnificus* levels from 100,000 MPN/g to the revised microbiological level of less than 30 MPN/g, result in a 3.52 log reduction in the pathogen. ISSC, with FDA concurrence, formally adopted the 3.52 log reduction to achieve the less than 30 MPN/g microbiological level for *V. vulnificus* in post-harvest processed shellfish products in the 2005 NSSP Guide.¹⁰

This regulatory proposal amends California’s regulations to be consistent with the current NSSP standards and adopts the less than 30 MPN/g microbiological level for *V. vulnificus*, achieved through a 3.52 log reduction performance standard.

Revised Laboratory Methods

Post-harvest processed oysters in California were originally validated using the FDA Bacteriological Analytical Manual (BAM) procedures for microbiological analyses at the less than 3 MPN/g level established by CCR Section 13675(a)(5) in 1997. In the decade since the adoption of California’s less than 3 MPN/g level, however, laboratory analyses have changed to take advantage of more rapid, sensitive, and selective methods. ISSC also established extensive procedures to formally evaluate and adopt laboratory methods for the analysis of shellfish. The efficacy and equivalency of a particular method must receive concurrence by the FDA prior to incorporation into the NSSP.

The 2009 NSSP Guide lists three approved methods for *V. vulnificus* enumeration in shucked and in-shell shellfish products:

Drafting Group and as a reviewer of the Vv Risk Assessment.

¹⁰ It was logistically difficult for shellfish dealers to obtain oysters at the 100,000/g level, even with temperature abuse. In response, ISSC established protocols for the 2005 NSSP enabling dealers to use an Adjusted Geometric Mean of 10,000 or greater with appropriate procedures for process and equipment validation and verification. Further explanation was subsequently provided in the 2009 NSSP.

- EIA procedure of Tamplin, et. al., as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992 (Type III);
- MPN method in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA-alkaline phosphatase labeled gene probe (vvhA)(Type III); and
- SYBR Green 1 QPCR-MPN.

The Department anticipates there will be continued development of innovative laboratory methods for the detection of *V. vulnificus* in post-harvest processed oysters. Determinations of equivalency such as accuracy, sensitivity, and precision, and approval of such new laboratory procedures are under the purview of appropriate, authoritative scientific bodies. These include the FDA, state shellfish programs, and recognized process authorities. The proposed revisions to CCR Section 13675(a)(8) require the evaluation and approval of new laboratory methods for the determination of *V. vulnificus* in post-harvest processed oysters by the FDA or a recognized process authority.

PROBLEMS ADDRESSED BY THIS PROPOSED REGULATORY ACTION:

CCR Section 13675 was adopted in 1991 to reduce illnesses and deaths associated with the bacterium *V. vulnificus* in raw Gulf oysters. The regulation's primary purpose was to provide consumer warnings at California retail locations selling raw Gulf oysters about the risks associated with the consumption of Gulf oysters that may contain the bacterium *V. vulnificus*. Subsequent revisions to CCR Section 13675 required consumer warnings be offered in Spanish and provided for exemptions from the warning requirements if the Gulf oysters had undergone a process to reduce *V. vulnificus* levels to less than 3 MPN/g.

Continued illnesses and deaths associated with raw Gulf oysters within California necessitated additional amendments to CCR Section 13675 resulting in the restriction of the sale of raw Gulf oysters harvested from April 1 through October 31, annually. However, the exemptions from retail warnings in CCR subsection 13675(d) and sales restrictions in CCR subsection 13675(c)(5)(A) for raw Gulf oysters processed to reduce *V. vulnificus* to less than 3 MPN/g remained in effect. CCR Section 13676 was adopted to provide procedures for requesting a verification by the Department that the oysters were subjected to post-harvest process as defined in subsection 13675(a)(8).

In 2001, FAO/WHO initiated a scientifically-based Vv Risk Assessment. The Vv Risk Assessment determined that significant reductions in infections among individuals at highest risk¹¹ could be realized if oysters were processed to a less than 30 MPN/g microbiological level for *V. vulnificus*. Based on the findings of this risk assessment,

¹¹ Persons considered at "high-risk" include those with chronic illnesses or those with compromised immune systems. Major risk factors include chronic liver diseases, including cirrhosis from alcohol consumption, diabetes, cancer, HIV/AIDS, hemochromatosis, chronic kidney disease and decreased resistance from the use of immunosuppressive drugs or steroids.

ISSC, with the concurrence of the FDA, revised the microbiological level for *V. vulnificus* in post-harvest processed oysters from less than 3 MPN/g to less than 30 MPN/g. The revised microbiological level was incorporated into the 2003 NSSP Guide.¹² In 2006, ISSC, with FDA concurrence, established a performance standard requiring the *V. vulnificus* reduction process to achieve the less than 30 MPN/g level through a minimum 3.52 log reduction.

Since 2003, California's *V. vulnificus* standard for processed oysters has been inconsistent with the level adopted by the FDA and ISSC. As a result, under the current subsection 13675(c)(5), Gulf oysters harvested during the period April through October, that are subsequently processed to less than 30 MPN/g, may not be sold in California at any time and are subject to regulatory action if found in commerce. However, oysters processed to less than 30 MPN/g that have been harvested from November through March may be sold at any time. Regulating oysters harvested during the period of restriction yet treated to reduce the level of *V. vulnificus* presents enforcement obstacles for the Department.

Importantly, with the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for post-harvest processed oysters. The discrepancy in standards between California (less than 3 MPN/g) and NSSP (less than 30 MPN/g) has put the Department in conflict with ISSC and the FDA. In 2005, the ISSC Executive Board determined that the Department was in violation of Procedure V or the "reciprocity" provisions of the ISSC Constitution¹³ and the ISSC membership subsequently concurred with this determination.¹⁴ At the 2005 ISSC meeting, the Department was formally censured, and the Conference imposed administrative sanctions on the Department that limits the Department's participation in the Conference.

The administrative sanctions imposed on the Department remain in effect. However, failure to adopt the revised microbiological level and performance standard may result in additional administrative sanction by ISSC with a formal recommendation to the FDA that California shellfish dealers be removed from the ICSSL for non-compliance with NSSP standards. The de-listing of California firms on the ICSSL would ostensibly restrict the out-of-state sale of shellfish originating from California and would authorize other states to take action on shellfish shipped from California sources. These sanctions, if enacted by the FDA, would result in a negative economic impact to the California shellfish industry including small businesses. The Department does not have

¹² Shellfish sanitation controls adopted by ISSC and receiving concurrence by the FDA are disseminated through NSSP Guides.

¹³ The ISSC Constitution, Procedure V, Guidelines state: "Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. Reciprocity, for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements".

¹⁴ Under the provisions of the NSSP, shellfish dealers found in compliance with the standards of the NSSP are eligible for listing on the ICSSL. The FDA administers the ICSSL as a means to assure states that shellfish shipped through interstate commerce meet minimum national standards for safety and labeling. The Department inspects California shellfish dealers who are engaged in interstate sales for compliance with NSSP standards, and firms meeting the standards are approved by the Department for listing on the ICSSL.

data to estimate the economic impact to shellfish dealers and small business. However, The Department is aware that many shellfish dealers provide shellfish to out-of-state customers, particularly within the State of Nevada, and a sanction that would eliminate those markets would pose a negative economic impact to California.

Adoption of the less than 30 MPN/g microbiological level, achieved through a 3.52 log reduction performance standard provides the Department with the authority to enforce a consistent public health standard for Gulf oysters that have been processed, irrespective of the harvest date (Tables 2 and 3).

Table 2. Sale of Gulf Oysters in California Current Provisions -- CCR Section 13675

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Raw, live, Oysters (untreated)												
Post-Harvest Processed Oysters less than 3 MPN/g												
Post-Harvest Processed Oysters less than 30 MPN/g												

- Sale permitted, consumer warning required
- Sale Permitted. Verification required. Exempt from warning requirements.
- Sale prohibited

Table 3. Sale of Gulf Oysters in California Revised Provisions -- CCR Section 13675

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Raw, live, Oysters (untreated)												
Post-Harvest Processed less than 3 MPN/g												
Post-Harvest Processed less than 30 MPN/g												

- Sale permitted, consumer warning required
- Sale Permitted. Verification required. Exempt from warning requirements.
- Sale prohibited

Finally, this proposed regulatory amendment could result in economic benefits to the shellfish industry in the form of reduced costs associated with processing oysters. The Department also anticipates that the California food industry may experience increased business with an increase in the amounts and varieties of post-harvest processed oysters imported into California.

Purpose of this Regulatory Proposal

The purpose of this regulatory proposal is to amend CCR Sections 13675 and 13676. The proposed amendment to CCR Section 13675 is primarily to subsection 13675(a)(8) and revises the microbiological level for *V. vulnificus* in post-harvest processed Gulf oysters from the current level of less than 3 MPN/g to less than 30 MPN/g. This regulatory amendment will require the less than 30 MPN/g microbiological level of *V. vulnificus* is met through a performance standard that achieves a minimum 3.52 log reduction. The proposed amendment to subsection 13675(a)(8) also revises the laboratory procedures employed for the detection and enumeration of *V. vulnificus* in post-harvest processed oysters to be consistent with the revised microbiological level.

The proposed amendments to CCR Section 13676 make subsection 13676(a)(4) consistent with the amendments to CCR Section 13675.

The proposed amendments harmonize California's molluscan shellfish regulations with the provisions adopted for the NSSP¹⁵ by the FDA and ISSC.¹⁶ With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for post-harvest processed oysters.

The amendments are consistent with the findings of the "Risk Assessment of *Vibrio vulnificus* in Raw Oysters" conducted by FAO/WHO. This determination is also supported by epidemiological data maintained by FDA. Since becoming commercially available in 2005, there have been no epidemiologically-linked *V. vulnificus* infections associated with raw oysters processed at the less than 30 MPN/g level documented by FDA.

The proposed amendments will likely result in the removal of sanctions against California by ISSC and avert the negative economic impact to California businesses that may result from additional administrative actions directed at California by ISSC and FDA. In addition, the amendments provide the Department with the authority to uniformly regulate raw oysters processed to less than 30 MPN/g, but harvested during different times of the year, while maintaining the current level of restriction on the sale of raw Gulf oysters harvested from the states of Alabama, Florida, Louisiana, Mississippi, or Texas during April through October. Additional benefits anticipated by the

¹⁵ The NSSP was developed to assist in the control of disease associated with the consumption of raw shellfish. The public health control procedures established by the NSSP are supported by the FDA and dependent on the cooperative efforts of state regulatory agencies and the shellfish industry.

¹⁶ ISSC is one of three FDA cooperative programs (shellfish, milk, and retail food) established to promote food safety. ISSC is composed of the FDA, state regulatory agencies including California, and the shellfish industry.

Department include a reduction of costs associated with processing oysters using certain technologies and an increase in the amounts and varieties of post-harvest processed oysters imported into California to the benefit of consumers.

Broad Objectives of this Regulatory Proposal

The broad objectives of this regulatory proposal are to:

- This regulatory proposal harmonizes California's molluscan shellfish regulations for post-harvest processed Gulf oysters with those of the NSSP, as adopted by the FDA and ISSC. The proposed revised standard is based on the determinations of the Vv Risk Assessment conducted the FAO/WHO. With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for post-harvest processed oysters.
- To provide a science-based standard for post-harvest processed oysters based on the Vv Risk Assessment conducted by the FAO/WHO.
- To provide for uniform regulatory enforcement for post-harvest processed oysters by allowing the sale of Gulf oysters, processed to less than 30 MPN/g, to be sold year-round, irrespective of harvest date.
- To provide clarity and consistency for the public and the oyster industry regarding oyster health and safety regulations.
- To establish performance based health and safety standards that meet concerns of public health officials, the public, and shellfish dealers.
- To protect the public health and safety of California consumers of oysters using scientific-based standards.

Benefits Resulting from this Proposed Regulatory Action

The anticipated major benefits, including nonmonetary benefits to the protection of public health and safety, worker safety, the environment, the prevention of discrimination, or the promotion of fairness or social equity, from this proposed regulatory action include:

- This regulatory proposal harmonizes California's molluscan shellfish regulations for post-harvest processed Gulf oysters with those of the NSSP, as adopted by the FDA and ISSC. The proposed revised standard is based on the determinations of the Vv Risk Assessment conducted the FAO/WHO. With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for post-harvest processed oysters.

- To establish performance based health and safety standards, using scientific research, that meet concerns of public health officials, the public, and shellfish dealers.
- To provide for uniform regulatory enforcement for post-harvest processed oysters by allowing the sale of Gulf oysters, processed to less than 30 MPN/g, to be sold year-round, irrespective of harvest date.
- To allow the Department to petition ISSC to remove current administrative sanctions against California.
- To prevent the imposition of administrative actions by FDA to remove California shellfish dealers from the ICSSL. This will avert economic harm to California shellfish dealers and allow for the unrestricted sale of shellfish into interstate commerce by California dealers.
- To potentially reduce the costs to treat oysters post-harvest.
- To potentially provide greater amounts and varieties of oysters that are processed for enhanced safety for the culinary enjoyment of Californians, especially those who are at high-risk for infection.
- To reduce confusion for the public and the oyster industry about oyster health and safety restrictions.
- To protect the public health and safety of California consumers of oysters using scientific-based standards.

Consistency and Compatibility with Existing State Regulations

The Department has evaluated whether the proposed regulations are inconsistent or incompatible with existing State regulations. This evaluation included a review of the Department's laws and specifically those statutes and regulations related to food health and safety and specifically the regulation of oysters. The Department staff also conducted an internet search of other State agency regulations and considered numerous research publications.

No known statute or regulation conflicts with this proposed regulatory update. The Department determined that no other State regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other State regulations. Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing State regulations.

REASONABLE ALTERNATIVES CONSIDERED:

To assess reasonable alternatives to the proposed regulations, the Department researched current industry standards and reviewed numerous public health research publications for updated information on *V. vulnificus* safety.

Alternative 1: Amend the CCRs to Change the Microbiological Level of *V. vulnificus* in Post-Harvest Processed Oysters.

This alternative would amend CCR Section 13675 to change the microbiological level of *V. vulnificus* in post-harvest process oysters to less than 30 MPN/g achieved through a minimum 3.52 log reduction and amend CCR Section 13676 to be consistent with the amendments in CCR Section 13675.

The Department has reviewed public health research on microbiological levels of *V. vulnificus*. This research includes data and findings from industry experts, the federal government, and international experts. The Department has determined that the proposed amendments are reasonable in light of this scientific data, analysis, and basis for the changes. The Department believes this alternative is reasonable with positive impacts on the California shellfish industry and public as follows:

- This regulatory proposal harmonizes California's Mollusca shellfish regulations for post-harvest processed Gulf oysters with those of the NSSP, as adopted by the FDA and ISSC. The proposed revised standard is based on the determinations of the Vv Risk Assessment conducted the FAO/WHO.
- This proposal allows the Department to petition ISSC to remove current administrative sanctions.
- This alternative prevents the imposition of administrative sanctions by FDA that would remove California shellfish dealers from the ICSSL and prevent California dealers from unrestricted sales of shellfish into interstate commerce.
- This alternative allows for the sale of Gulf oysters, processed to less than 30 MPN/g, to be sold year-round, irrespective of harvest date.
- This alternative will likely reduce the cost to post-harvest process oysters associated with certain available technologies.
- This alternative is reasonable and positive in that it will likely provide greater amounts and varieties of oysters for consumption by Californians and processed for enhanced safety, especially to those who are "high risk" for infection.

If a *V. vulnificus* case were to occur in California, certain sectors of private industry and government may be affected by the proposed amendments. FAO/WHO estimates 1.2 *V. vulnificus* cases per year within the United States, resulting from the consumption of oysters post-harvest processed to less than 30 MPN/g, in individuals at highest risk. The costs associated with a single *V. vulnificus* case have been estimated at approximately 3 million dollars. In the event such a case occurs in California, these costs would be incurred by insurance companies, public agencies, and/or individuals. The Department estimates additional costs to local and state health agencies of \$1,449 and \$3,067, respectively, to investigate each *V. vulnificus* infection.

The Department has weighed the possibility of increased *V. vulnificus* infections and the cost of treatment versus the various benefits of this proposed regulatory action including harmonizing California's requirements for post-harvest processed Gulf oysters with national standards. Given the lack of cases reported by FDA at the less than 30 MPN/g standard, the benefits of this regulatory proposal, and the scientific data that support the revised standard, the Department has determined that this proposed regulatory action is reasonable and the best alternative available.

Alternative 2, The No Change Alternative: Maintain the Current Regulatory Standard for Post-Harvest Processed Oysters.

The Department has considered maintaining the status quo and current microbiological level for post-harvest processed Gulf oysters at the less than 3 MPN/g standard. The Department's research shows the No Change Alternative will result in the following:

- California's censure by ISSC will continue indefinitely, causing economic harm to California's shellfish industry.
- Additional administrative actions may be taken by FDA to remove California shellfish dealers from the ICSS List, again causing economic harm to California's shellfish industry.
- Gulf oysters harvested during April through October and subsequently processed to less than 30 MPN/g will remain restricted from sale. This will continue to cause enforcement problems for regulators.

The Department had determined that the No Change Alternative is not reasonable in light of the FAO/WHO Vv Risk Assessment determination, continuing enforcement confusion, and negative economic impacts to the shellfish industry, California's economy, and small businesses.

Detailed Discussion of the Specific Purpose, Rationale and Problem Addressed for Each Regulation Proposed for Amendment, Adoption or Repeal:

Section 13675. Definitions: This section provides definitions of terms used in the regulations. The amendments to these definitions are reasonably necessary to provide for uniform interpretation of the text, consistency in the terminology used in the proposed regulations, and to effectuate the purposes of the oyster statutes. New definitions are proposed for adoption and outdated or unnecessary definitions are proposed for deletion. The definitions have also been relocated and renumbered so they are placed in alphabetical order.

Subsection 13675(a)(1): This proposal amends subsection (a)(1) to refer to the correct HSC Section. In May 2006, Senate Bill (SB) 144 enacted the California Retail Food Code [CRFC], (HSC Sections 113700 – 114437) replacing the California Retail Food Facilities Law (HSC Sections 113700 – 114475). The revision to subsection (a)(1) is

necessary to reflect the changes in the HSC Section number for the regulatory text contained in the CRFC that became effective July 1, 2007.

Subsection 13675(a)(2): This proposed amendment adds clarity to the regulations by defining FDA and by placing that definition in alphabetical order. The definition for “Gulf oyster” previously contained in subsection (a)(2) is relocated and renumbered to be in alphabetical order as subsection (a)(3) for clarity.

Subsection 13675(a)(3): The definition “Half-shell oyster” previously contained in subsection (a)(3) is relocated and renumbered as subsection (a)(4). This amendment is necessary to place this term in alphabetical order for clarity.

Subsection 13675(a)(4): The definition “MPN” or “Most Probable Number” previously contained in subsection (a)(4) is relocated and renumbered as subsection (a)(5). This amendment is necessary to place this term in alphabetical order for clarity.

Subsection 13675(a)(5): This subsection is amended to move the definition of “Non-detectable level” into the definition of “Oyster treatment process” in subsection (a)(8). This amendment is necessary to consolidate the performance standards for post-harvest processed oysters and thereby provide clarity of the standards for the shellfish industry and regulation users. This amendment also relocates the definition of “MPN” or “Most Probable Number” from subsection 13675(a)(4) to this subsection. This amendment places this term in alphabetical order for clarity.

Subsection 13675(a)(8): This amendment is necessary to make this subsection consistent with the acronym for the FDA found in the definitions subsection 13675(a)(2).

This subsection is also amended to implement a specific, scientifically-based performance standard of less than 30 MPN per gram with a minimum 3.52 log reduction in processed oysters. This amendment is necessary to harmonize California’s standard for *V. vulnificus* in post-harvest processed oysters with NSSP and FDA recommendations.

Additionally, this proposed amendment allows new laboratory methods to be used when testing oysters if deemed equivalent in terms of accuracy, precision, and sensitivity to the EIA procedure of Tamplin et al. as described in Chapter 9 of the *FDA Bacteriological Analytical Manual*, 7th edition, 1992. This amendment is necessary to permit the shellfish industry to utilize new, often more sensitive and less expensive performance based analytical methods for *V. vulnificus*.

This amendment is also necessary to address the dynamic nature of laboratory method development and approval. The proposed language is necessary to identify the current approved laboratory method for detection and enumeration of *V. vulnificus*, while allowing for the acceptance of future laboratory methods only if deemed equivalent by ISSC and FDA.

Subsection 13675(a)(9): This amendment deletes the text “U.S. Food and Drug Administration” and replaces it with the acronym “FDA” previously defined in amended subsection (a)(2). This amendment is necessary to make this subsection consistent with the acronym for the FDA defined in subsection 13675(a)(2).

Subsection 13675(a)(10): This regulatory proposal amends subsection (a)(10) to refer to the correct HSC Sections. The revisions to subsection (a)(10) are necessary to reflect the changes in the HSC Section numbers for the regulatory text contained in the CRFC that became effective July 1, 2007.

Subsection 13675(i): This subsection is amended to replace the phrase “processed to reduce *Vibrio vulnificus* to a non-detectable level” with the phrase “subjected to an oyster treatment process described in subsection (a)(8).” This amendment is necessary to be consistent with the revision in microbiological level to less than 30 MPN/g and the performance standard of 3.52 log reduction contained in the amended subsection (a)(8).

Section 13675 Authority and Reference Citations: Authority and reference citations proposed for amendment are non-substantive changes, unless noted. These amendments are necessary to update the oyster regulations to reflect the statutory numbering system implemented by the 1995 recodification of the HSC and the reorganization of the Department of Health Services into Health Care Services and the Department of Public Health, pursuant to SB 162. (Stats. 2006, ch. 241.) For new HSC Sections regulating oysters, these authority and reference citations have been added. These additions are necessary to provide clarity to the public and regulation users as to the authority and references associated with this regulatory proposal and to provide consistency between the CCR and HSC provisions.

Subsection 13676(a)(4): This amendment deletes the text “U.S. Food and Drug Administration” and replaces it with the acronym “FDA” previously defined in amended subsection (a)(2). This amendment is necessary to make this subsection consistent with the acronym for the FDA defined in subsection 13675(a)(2).

In addition, the amendments to this subsection delete the phrase “non-detectable level” and replaced those words with the specific performance standard of less than 30 MPN/g and the minimum log reduction of 3.52 consistent with amended subsection 13675(a)(8). This amendment is necessary to harmonize California’s standard for *V. vulnificus* in post-harvest processed oysters with the NSSP and to make California’s oyster regulations consistent.

Subsection 13676(g): The current subsection (g) is deleted. As written, subsection (g) was consistent with provisions contained in Government Code Section 15376, which has been repealed. Subsection (g) is replaced with previously designated subsection (h) for clarity and to avoid a gap in the oyster regulations.

Subsection 13676(h): Current subsection (h) is relocated and renumbered to be the new subsection 13676(g). The phrase “to non-detectable levels” is replaced with the phrase “meet the *Vibrio vulnificus* reduction standards in subsection 13675(a)(8)”.

This change is necessary for consistency with the changes proposed to subsection 13675 (a)(8).

The sentence “The department shall inform the dealer of any denial, revocation, or suspension in writing, stating the reasons for the denial, revocation, or suspension.” is relocated to replace the previously numbered subsection (i), with this portion of re-numbered subsection (h). This change is necessary to provide continuity between subsections and to separate oyster treatment standards from enforcement notification procedures. This separation is necessary to provide more clarity for the public.

Subsection 13676(i): Subsection (i) is deleted and the substance is relocated to subsection (h). The word “dealer” and the phrase “of any verification” are necessary to add specificity and thus clarity for the public and regulation users.

Section 13676 Authority and Reference Citations: Authority and reference citations proposed for amendment are non-substantive changes, unless noted. These amendments are necessary to update the oyster regulations to reflect the statutory numbering system implemented by the 1995 recodification of the HSC and the reorganization of the Department of Health Services into Health Care Services and the Department of Public Health, pursuant to SB 162. (Stats. 2006, ch. 241.) For new HSC Sections regulating oysters, these authority and reference citations have been added. These additions are necessary to provide clarity to the public and regulation users as to the authority and references associated with this regulatory proposal and to provide consistency between the CCR and HSC provisions.

**TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS
OR DOCUMENTS RELIED UPON:**

California Department of Health Services, California Conference of Local Health Officers (CCLHO). [Board of Directors, Meeting Minutes, Sacramento, CA, August 4, 2005](#). Print.

California Department of Health Services, California Conference of Local Health Officers (CCLHO). [Environmental Health Committee, Meeting Minutes, Sacramento, CA, July 26, 2007](#). Print.

Hoffman, Sandra, Batz, Michael B., and Morris, Jr., Glenn. [Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States Due to 14 Foodborne Pathogens](#). *Journal of Food Protection*, Vol. 75, No. 7, 2012, pages 1292-1302. Print.

Interstate Shellfish Sanitation Conference. [Constitution, By-Laws and Procedures, Page 20, Received by e-mail from ISSC](#). June 27, 2005. Print.

Interstate Shellfish Sanitation Conference. *Minutes of Executive Board Meeting, August 14, 2005*. Print

Interstate Shellfish Sanitation Conference. *Minutes of Executive Board Meeting, August 15, 2005*. Print.

Interstate Shellfish Sanitation Conference. [Report of the Vibrio vulnificus Post-Harvest Treatment Validation/Verification Working Group](#), July 18, 2002. Print.

Interstate Shellfish Sanitation Conference, *Vibrio vulnificus* Subcommittee. *Report for the 08/3/03 Vibrio vulnificus Subcommittee Meeting*, 2003. Page 21. Print. Website: http://www.issc.org/client_resources/Committees/VibriovulnificusSubcommitteeReport08-03-2003.pdf.

Moore, Ken B. [California Regulation Title 17 Section 13676](#). Interstate Shellfish Sanitation Conference, Internal Memo to the ISSC Executive Board, June 24, 2005. Print.

United Nations, World Health Organization, Food and Agriculture Organization. *Microbiological Risk Assessment, Series 8, Risk Assessment of Vibrio vulnificus in Raw Oysters, Interpretative Summary and Technical Report*. Rome: World Health Organization, 2005. Print. <http://www.who.int/foodsafety/publications/micro/mra8.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration. *Interstate Certified Shellfish Shipper's List, 2013*. Print. <http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006753.htm>

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *NSSP 2009 Section III. Public Health Reasons*

and Explanations, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2009, Section III (pg. 129). Public Health Reasons and Explanations, Chapter XVI. Background & Performance of Post Harvest Processing (PHP) Validation/ Verification Protocols (pg. 172). Print.
<http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM350004.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration. *Shellfish-Related Vibrio vulnificus Cases/Deaths, 2005 – 2012.* Print

U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. [National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, Model Ordinance, 1997 Revision, Chapters: XI.03.J, Post-Harvest Processing, Page 89; XII.03.H, Post-Harvest Processing, Page 99; and XIII.03.H, Post-Harvest Processing, Page 110.](#) Print.

U.S. General Accountability Office. *Food Safety, FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters.* Report to the Honorable Rosa L. DeLauro, House of Representatives, GAO-11-607. Washington: September 2011.
<http://www.gao.gov/assets/520/511457.pdf>

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. *National Shellfish Sanitation Program, [Guide for the Control of Molluscan Shellfish, 2003, Model Ordinance, Chapter XVI.](#) Post-Harvest Processing.* Print.

U.S. Department of Health and Human Services, Food and Drug Administration Center for Food Safety and Applied Nutrition. [National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2005, Chapter II., Model Ordinance, Chapter XVI., Post-Harvest Processing.](#) Print.

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. [National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2005, Chapter IV., Guidance Documents, Naturally Occurring Pathogens.](#) Print.

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. [National Shellfish Sanitation Program, 2009 Sec. IV., Chap II, 10 Approved National Shellfish Sanitation Program Laboratory Tests, National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish, 2009, Section IV., Guidance Documents, Chapter II.](#) Print.

ADVISORY GROUP OR OTHER AGENCY COMMENT, CONSULTATION AND/OR APPROVAL, INCLUDING CALIFORNIA CONFERENCE OF LOCAL HEALTH OFFICERS:

This proposal is supported by the California Conference of Local Health Officers.

**STATEMENT OF THE ECONOMIC IMPACT AND EVIDENCE SUPPORTING
FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT
DIRECTLY AFFECTING BUSINESS:**

As to these proposed regulations, the Department has made an initial determination that no reasonable alternative considered or otherwise identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed, or would be as effective as and less burdensome to affected private persons than the proposed action or would be more cost effective to affected private persons, or as effective in implementing the intent of the HSC Sections 109875, 110105 and 113700 that regulate food sanitation and oyster safety in California.

ECONOMIC IMPACT ANALYSIS

Economic Impact on Business

The Department has made an initial determination that the proposed regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Based on the economic impact analysis, the Department has determined that the regulation would not significantly affect the following:

1. The creation or elimination of jobs within the State of California.
2. The creation of new businesses or the elimination of existing businesses within the State of California.
3. The expansion of businesses currently doing business within the State of California.
4. The benefits of the regulation to the health and welfare of California residents, worker safety, and the states environment.

Effect on Small Businesses

This regulatory proposal does not impact most small businesses in California as defined by Government Code Section 11342.610. The Department has determined that there may be, however, a financial benefit for some shellfish small businesses as a result of adopting this regulatory proposal. California businesses may sell more oysters by being able to sell greater amounts and varieties of oysters, processed to less than 30 MPN/g, year-round, irrespective of harvest date. The Department anticipates that this regulatory proposal will prevent the imposition of administrative sanctions by the FDA such as removing California shellfish dealers from the ICSSL which would negatively impact some small businesses. This regulatory proposal will also avert economic harm to California shellfish dealers by allowing the unrestricted sale of oyster into interstate commerce by California dealers. In addition, it is possible some businesses may reduce treatment costs due to performance based treatment technologies.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulations are reasonably necessary to protect the health and welfare of California consumers of raw oysters.

STATEMENTS OF DETERMINATIONS

LOCAL MANDATE DETERMINATION

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

FISCAL IMPACT ESTIMATE

1. Fiscal Impact on Local Government: None. The Department is not aware of any cost impacts that a local government agency would necessarily incur in reasonable compliance with the proposed action.
2. Fiscal Impact on State Government: Yes. The Department anticipates potentially reviewing and approving approximately 9 shellfish processing applications the first year and an unknown number in subsequent fiscal years. The application review is not a new program nor is it an increase in the scope of the existing program nor will these applications necessarily be submitted and the costs incurred. The Department is not aware of any other cost impacts that State government would necessarily incur in reasonable compliance with the proposed action.
3. Fiscal Impact on Federal Funding of State Programs: None.
4. Fiscal Impact on Private Persons or Businesses Directly Affected: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.
5. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: There are no known costs or savings imposed on local agencies in connection with this proposed regulatory package.

HOUSING COSTS DETERMINATION

The Department has determined that the proposed regulations will not have a financial impact on housing.

REASONABLE ALTERNATIVES STATEMENT

In accordance with Government Code Section 11346.5(a)(13), The Department has determined that no reasonable alternative considered or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which this action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

In accordance with Government Code subsection 11346.2(b)(5)(B), the Department has not identified any reasonable alternative that would lessen any adverse impact on small business because the Department believes the proposed regulations will not negatively affect small businesses.