



State of California—Health and Human Services Agency
California Department of Public Health



RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING

Title 17, California Code of Regulations

Raw Gulf Oysters, DPH-06-006

Notice Published June 27, 2014

PUBLIC PROCEEDINGS

The California Department of Public Health (Department) is conducting a written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department. The written comment period closes at 5:00 p.m. on August 11, 2014. The Department will consider only comments received at the Department's Office of Regulations at that time.

Written comments may be submitted as follows:

1. By email to regulations@cdph.ca.gov. Please place the regulation package identifier "DPH-06-006" in the subject line;
2. By fax transmission to (916) 440-5747;
3. By postal service to Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or,
4. Hand-delivered to Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address.

AUTHORITY AND REFERENCE

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, *Vibrio vulnificus* (*V. vulnificus*), 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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Department is 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.

This 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 *V. vulnificus*, 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 amend subsections 13675(a)(8) and 13676(a)(4), Title 17, of the California Code of Regulations (CCR). 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 amendment will require that the less than 30 MPN/g 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 subsection 13676(a)(4) make its wording consistent with the amendments to CCR Section 13675.

These proposed amendments harmonize California's molluscan shellfish regulations with the provisions adopted for the National Shellfish Sanitation Program (NSSP) by the U.S. Food and Drug Administration (FDA) and Interstate Shellfish Sanitation Conference (ISSC). With the exception of California, all member states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for *V. vulnificus* in post-harvest processed oysters.

The proposed regulatory amendments are consistent with the findings of risk determined 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.

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 that may be assessed on 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. This proposal maintains the current level of restriction on the sale of raw¹ 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.

OBJECTIVES

The broad objectives of this regulatory proposal are:

- To harmonize 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 by 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 *V. vulnificus* in post-harvest processed oysters.
- To provide a science-based standard for post-harvest processed oysters based on a 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

The anticipated major benefits, including nonmonetary benefits such as the protection of public health and safety, worker safety, the environment, the prevention of discrimination, or the promotion of fairness or social equity, and the increase in transparency in business and government among other things, from this proposed regulatory action include:

- To harmonize 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

¹ 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*.

states and countries of ISSC have adopted the less than 30 MPN/g microbiological level for *V. vulnificus* 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 the ISSC to remove current administrative sanctions against California.
- To prevent the imposition of administrative actions by the 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 processed for enhanced safety for the culinary enjoyment of Californians, especially those who are high-risk for infection.
- To reduce confusion for the public and the oyster industry about oyster health and safety restrictions.
- To assist the efforts of the FDA and the ISSC in their efforts to promote oyster post-harvest treatment technologies to provide additional choices to high-risk individuals nationwide.
- To protect the public health and safety of California consumers of oysters using scientifically-derived standards.

INCONSISTENT/INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to food health and safety, specifically the regulating of oysters. An internet search of other state agency regulations was also performed. It was determined that no other regulation addressed the same subject matter, and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, it is determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the regulations.

FORMS INCORPORATED BY REFERENCE

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

LOCAL MANDATE

The Department has determined that the regulations 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

- A. Fiscal Effect on Local Government or School District: None.
- B. Fiscal Effect on State Government: Yes. The Department anticipates potentially reviewing and approving approximately 9 shellfish processing applications the first year and unknown number subsequent fiscal years. The application review is not a new program or increasing the scope of the existing program nor will these applications necessary 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.
- C. Fiscal Effect on Federal funding of state programs: None.
- D. 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.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS

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.

HOUSING COSTS

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

SIGNIFICANT, STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY OF CALIFORNIA BUSINESSES TO COMPETE WITH BUSINESSES IN OTHER STATES

The Department has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

SMALL BUSINESS

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 the 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 that 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.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS/ASSESSMENT

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 regulations to the health and welfare of California residents, worker safety, and the state's environment.

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.

BUSINESS REPORTING REQUIREMENT

No Report Required.

ALTERNATIVES INFORMATION

As to these proposed regulations and in accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department 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 the regulatory action is proposed, would be as effective and less burdensome to affected private persons than the proposed regulatory action; or, would be more cost effective to affected private persons, and equally effective in implementing the intent of the statutory policy or other provision of law. Alternatives considered in this proposal are addressed in the Initial Statement of Reasons.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Pat Kennelly, Chief, Food and Drug Branch, Food Safety Section, at (916) 650-6598.

All other inquiries concerning this notice may be directed to Laurel Prior, Office of Regulations, at (916) 440-7673.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents, please call (916) 440-7673 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

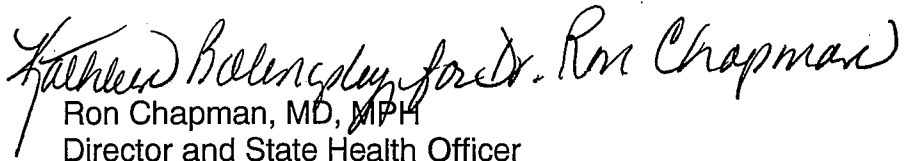
A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Materials regarding the action described in this notice (including this public notice, the regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunity for Public Participation, Proposed Regulations.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

Date:


Ron Chapman, MD, MPH
Director and State Health Officer