Final Statement of Reasons
Raw Gulf Oyster Regulations
Title 17, California Code of Regulations (CCR)

The information contained in the Initial Statement of Reasons (ISOR) at the time of Public Notice remains unchanged with the exception of the following modifications. The ISOR is incorporated by reference in the Final Statement of Reasons.

Section 13675(a)(8): was modified to clarify that analytical methods utilized to verify the effectiveness of the oyster treatment process other than the *Vibrio vulnificus* EIA procedure of Tamplin et al. as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th edition, 1992, that are determined to be at least as equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *Vibrio vulnificus*, would be determined by the state shellfish authority having jurisdiction, FDA or a recognized process authority. This text was inserted to clarify the regulatory language and make it consistent with the presentation of the information in the initial statement of reasons.

Section 13675(a)(8): was also modified to add required language and a "link" for the incorporation of the analytical method by reference into the regulation. These changes are without regulatory effect.

Non substantial changes to punctuation, format, and wording were made to the following sections:

Section 13675(a)(10): In the phrase ". . . as defined in ~~s~~Section 11378~~5~~9 . . .[,]" the "~~s~~" and "ection" should not have been underlined, therefore the underline was removed.

Section 13676(h): In the phrase ". . . meet the *Vibrio vulnificus* reduction standards[,]" the term "*Vibrio vulnificus*" should not have be underlined, therefore the underline was removed.

Section 13676(h): There should have been a comma following "~~to non-detectable levels,~~" therefore a comma was inserted after that phrase.

Section 13676(h): The word "~~dealer~~" being repealed from the last sentence should have been "person," therefore the wording was updated accordingly.

Section 13676(i): There is no pre-existing subdivision (i), so the inadvertent strikeout of (i) was removed from the text.

Section 13676 (Authority and Reference citations): There should have been an "and" following "~~Section 15376, Government Code; and~~," therefore an "and" was inserted into the text.

These changes are without regulatory effect.

ISOR page 18: The last sentence on page 18 indicated that other laboratory methods, other than those specified in the text of the regulation would be accepted if deemed equivalent by "ISSC and FDA." The reference to ISSC was incorrect and the sentence is being corrected by striking through "ISSC and" and adding the phrase ", the state shellfish control authority having jurisdiction, or a recognized process authority." immediately after the "FDA." This change makes this statement consistent with other references made in the Initial Statement of Reasons relative to approval of oyster treatment processes and laboratory methods. This is a change without regulatory effect.

SUMMARY AND RESPONSES TO COMMENTS RECEIVED DURING THE INITIAL 45-DAY NOTICE OF PROPOSED RULEMAKING PERIOD FROM JUNE 27, 2014 THROUGH AUGUST 11, 2014

The Department complied with the provisions of Government Code section 11346.4, subdivision (a) (1) through (4), regarding the mailing of the notice of proposed regulatory action. The notice mailed on June 25, 2014, over 45 days prior to the close of the public comment period, which was on August 11, 2014. The notice and proposed regulation text were available to the public during the comment period from June 27, 2014 through August 11, 2014, at the CDPH Office of Legal Services, 1415 L Street, Suite 400, Sacramento, CA, between the hours of 8:00 a.m. and 5:00 p.m. and on the CDPH web site. Since there were no requests for a public hearing, one was not held. Four comments received are listed as follows:

List of Commenters During Initial 45-Day Public Comment Proceeding (from June 27, 2014 through August 11, 2014) (Written Testimony)

1. Margaret Pilaro Barrette, Pacific Coast Shellfish Growers Association
2. David W. Plunkett, J.D., J.M., Center for Science in the Public Interest
3. Lisa M. Weddig, National Fisheries Institute
4. Ken B. Moore, Interstate Shellfish Sanitation Conference

Summary of Comments and Responses

Note: The first digit of the number designation identifies the Commenter as listed above. The digit(s) after the decimal point indicate the identified comment from that commenter.

1.1 Commenter indicates support for adoption of the proposed regulations.

Response: California Department of Public Health appreciates the indication of support for adoption of the proposed regulations.

2.1 Commenter recommends that California Department of Public Health retain its current microbiological level for *Vibrio vulnificus* in post-harvest processed Gulf oysters at less than 3 MPN/g as it is most protective of public health.

Response: The Food and Agriculture Organization of the World Health Organization (FAO/WHO) (2005) Risk Assessment of *Vibrio vulnificus* in Raw Oysters, Interpretative Summary and Technical Report (as referenced in the ISOR, pg. 21) indicated that a *Vibrio vulnificus* concentration of less than 30 MPN/g is a negligible health risk. The FAO/WHO findings serve as one of the primary factors considered in the adoption of the proposed regulation to modify the current *Vibrio vulnificus* concentration of less than 3 MPN/g to less than 30 MPN/g. 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 (as referenced in the ISOR, pg. 22). No change is needed to the proposed regulation.

2.2 Commenter indicates it is unlikely that the existing less than 3 MPN/g level poses a hardship on processors and that relaxing the standard would result in the current post harvest processors that are achieving the 3 MPN/g to adjust their processes to the 30 MPN/g level so they can remain competitive with other business entities that will try to initiate sales into California under the new standard.

Response: Some existing dealers may opt to modify their post-harvest treatment processes to meet the less restrictive standard of less than 30 MPN/g as a means of controlling their costs and remaining competitive in the marketplace. Gulf Oysters processed to less than 30 MPN/g levels are currently allowed to be sold in California during the months of November through March, so under the proposed regulation, dealers that provide post-harvest treatments to oysters will now have a consistent processing threshold throughout the year. No change is needed to the proposed regulation.

2.3 Commenter indicates that modification of the regulatory standard for post-harvest treated oysters to less than 30 MPN/g may result in more illnesses.

Response: The FAO/WHO (2005) Risk Assessment of *Vibrio vulnificus* in Raw Oysters, Interpretative Summary and Technical Report determined the total number of predicted illnesses for high-risk individuals consuming oysters treated to less than 3 MPN/g, and less than 30 MPN/g, was 0.16 cases per year (one *V. vulnificus* case per 10 million meals), and 1.2 cases/year (8 per 10 million meals), respectively. While the predictions indicate a minute increase to 1.2 illnesses per year nationwide, 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 since they became available in 2005. No change is needed to the proposed regulation.

2.4 Commenter indicates that there is no enforcement obstacle by maintaining the current regulatory standard and the only valid reason for making this change

to the regulatory standard is a threat from the Interstate Shellfish Sanitation Conference to have California shellfish dealers delisted for the state's non-compliance.

Response: There are a number of contributing factors that serve as the reasons for the adoption of the proposed regulations. The risk of California shellfish dealers being delisted is real, but would not serve as the primary basis for making a change to the regulations and would certainly not override concerns over the public health impacts of the proposed requirements. The reasons for amending the regulations has been thoroughly addressed in the *Initial Statement of Reasons for Proposed Raw Oysters Regulations* document, dated October 4, 2013; specifically, under the headings "Broad Objectives of this Regulatory Proposal" and the "Benefits Resulting from this Proposed Regulatory Proposal." No change is needed to the proposed regulations.

2.5 Commenter indicates that adopting a 30 MPN/g level, would likely lead to frozen post-harvest processed oysters to have higher levels of *Vibrio vulnificus* than those processed under a frozen post-harvest processing method to reduce the levels to less than 3 MPN/g.

Response: California Department of Public Health appreciates your comment and concurs that slightly higher levels of *Vibrio vulnificus* are possible when processing oysters to a less stringent level, however the Department does not believe there is a significant increase in the risk of illness associated with consumption of such products, for the reasons set forth in the initial statement of reasons.

3.1 Commenter indicates support for adoption of the proposed regulations.

Response: California Department of Public Health appreciates the indication of support for adoption of the proposed regulations.

4.1 Commenter indicates support for adoption of the proposed regulations.

Response: California Department of Public Health appreciates the indication of support for adoption of the proposed regulation.

NO COMMENTS RECEIVED DURING THE 15-DAY NOTICE OF PUBLIC AVAILABILITY PERIOD

On January 8, 2015, the Department mailed the modified text of the regulations with a notice of public availability to those persons specified in subsections (a) (1) through (4) of Section 44 of Title 1 of the CCR. The notice of availability and the modified text were available to the public from January 8, 2015 through January 24, 2015, at the CDPH Office of Legal Services, 1415 L Street, Suite 400, Sacramento, CA, between the hours of 8:00 a.m. and 5:00 p.m. and on the CDPH web site. The public comment period for the modified text was from January 8, 2015 through January 24, 2015. There were no comments or requests for a public hearing received.

Imposition of 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.

Alternatives Determination

The Department has determined that no alternative it considered would be more effective in carrying out the purpose for which the regulation is proposed, 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 and equally effective in implementing the statutory policy or other provision of law.

Impact on Business

The Department has determined that the regulation would not have a significant, statewide adverse economic impact directly effecting business, including the ability of California businesses to compete with businesses in other states.

Additional Material Added to Rulemaking File

1) Supplement to the Statement of Reasons.
2) Document incorporated by reference: *Chapter 9 of the FDA, Bacteriological Analytical Manual*, 7th Edition, 1992, is being incorporated by reference after the end of the 45-day comment period, but was made available during the 15-day comment period.

Incorporation by Reference

It would be too cumbersome to print the 30 pages of *Chapter 9 of the FDA, Bacteriological Analytical Manual*, 7th Edition, 1992 into the California Code of Regulations (CCR), and is therefore incorporated by reference.