

**SUPPLEMENT TO THE STATEMENT OF REASONS
DPH-06-006, 15-Day Public Availability**

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations as discussed below.

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 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 sSection 1137859 . . . [,]” 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Section 13676(h): The word “dealer” being repealed from the last sentence should have been “person,” therefore the wording was updated accordingly.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.

The last sentence on page 18 of the Initial Statement of Reasons 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.