Title 17. Public Health
Division 1. State Department of Health Services
Chapter 5. Sanitation (Environmental)
Subchapter 2. Foods and Drugs
Group 1. Rules and Regulations
Article 10.5. Raw Oysters

Amend Section 13675 to read as follows:

§13675. Raw Gulf Oysters: Labeling, Written Warnings and Additional Requirements.

(a) For purposes of this article, the following definitions shall apply:

(1) "Dealer" means a person who shucks, packs, re-packs, processes, labels, re-labels, ships, re-ships, holds or otherwise sells shellfish. "Dealer" does not include persons solely engaged in retail activities as defined in the Health and Safety Code, Section 1138~~7~~9<u>5</u>.

(2) ~~"Gulf oyster" means any oyster harvested from the states of Alabama, Florida, Louisiana, Mississippi, or Texas.~~ <u>"FDA" means the United States Food and Drug Administration.</u>

(3) ~~"Half-shell oyster" means any oyster from which one shell has been removed.~~ <u>"Gulf oyster" means any oyster harvested from the states of Alabama, Florida, Louisiana, Mississippi, or Texas.</u>

(4) ~~"MPN" (Most Probable Number) means a statistical estimate of the number of bacteria per unit volume determined from the number of positive results in a series of fermentation tubes.~~<u>"Half-shell oyster" means any oyster from which one shell has been removed.</u>

(5) ~~"Non-detectable level" means that the MPN of *Vibrio vulnificus* bacteria is less than 3 MPN per gram of product as determined by the *Vibrio vulnificus* testing method in the U.S. Food and Drug Administration Bacteriological Analytical Manual, 8th Edition, 1995, pages 9.01-9.27, hereby incorporated by reference.~~<u>"MPN" (Most Probable Number) means a statistical estimate of the number of bacteria per unit volume determined from the number of positive results in a series of fermentation tubes.</u>

(a)(6)-(a)(7) No change to text

(8) "Oyster treatment process" means a process that has been determined by the state shellfish control authority having jurisdiction, the ~~U.S. Food and Drug~~

~~Administration~~FDA, or a recognized process authority to consistently reduce the level of *Vibrio vulnificus* to ~~a non-detectable level~~ less than 30 MPN per gram and achieve a minimum 3.52 log reduction in processed oysters, as determined by the use of the *Vibrio vulnificus* EIA procedure of Tamplin et al. as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th edition, 1992, which is hereby incorporated by reference, or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *Vibrio vulnificus* as determined by the state shellfish control authority having jurisdiction, the FDA, or a recognized process authority.

(9) "Recognized process authority" means the person(s) or organization(s) recognized by the state shellfish control authority or the ~~U.S. Food and Drug Administration~~FDA as having expert knowledge of oyster treatment processes, and having adequate facilities for making such determinations.

(10) "Retail food facility" means "retail" as defined in ~~s~~Section 1138~~7~~95 of the Health and Safety Code and "food facility" as defined in ~~s~~Section 1137~~5~~9 of the Health and Safety Code.

(a)(11)-(a)(14) No change to text

(b)-(h) No change to text

(i) A dealer who has received verification pursuant to Section 13676 shall affix to each container of raw Gulf oysters ~~processed to reduce *Vibrio vulnificus* to a non-detectable level~~subjected to an oyster treatment process described in subsection (a)(8), a tag or label pursuant to subsections (c)(2), (c)(3), and (c)(4), as required. In addition to requirements of subsections (c)(2), (c)(3), and (c)(4), such tag or label shall clearly and prominently bear the phrase "PROCESSED TO REDUCE VIBRIO VULNIFICUS TO NON-DETECTABLE LEVELS", followed by a lot number traceable to the dealer's processing records. Use of the phrase "PROCESSED TO REDUCE VIBRIO VULNIFICUS TO NON-DETECTABLE LEVELS", or words of similar meaning on tags or labels of raw unprocessed oysters, or on tags or labels of processed raw oysters from other than a dealer who has a current verification from the department is unlawful, and causes the oysters to be misbranded.

NOTE: Authority cited: Sections ~~100275,~~ 110065, 110105, 110430, 112165, ~~and~~ 1137~~1~~07, 131050, 131051, 131052, 131055, 131056, and 131200, ~~H~~Health and Safety Code. Reference: Sections 110175, 110545, ~~112165(c),~~ 110560, 110565, 110660, 110705, 112195, 112200, ~~and~~ 113980, 114029, 114039, 114039.1, 114039.2, 114039.3, and 114039.4, ~~H~~Health and Safety Code.

Amend Section 13676 to read as follows:

§13676. Request for Verification.

(a) A request for verification by the department that oysters supplied by a dealer are subjected to an oyster treatment process shall include all of the following:

(a)(1)-(a)(3) No change to text

(4) A report by the Shellfish Control Authority or a recognized process authority, accompanied by the concurrence of the ~~U.S. Food and Drug Administration~~FDA verifying that the process used consistently reduces the level of *Vibrio vulnificus* to ~~a non-detectable level~~less than 30 MPN per gram and achieves a minimum 3.52 log reduction in processed oysters.

(a)(5)-(f) No change to text

(g) ~~The time periods for processing a request for verification from the date of receipt by the department are as follows:~~

~~(1) The median time for processing a request is 45 days.~~

~~(2) The minimum time for processing a request is 20 days.~~

~~(3) The maximum time for processing a request is 60 days.~~

~~(h)~~ The department may revoke or suspend a verification granted pursuant to sub~~S~~section 13675(e) and this section for any failure of the dealer to ensure the use of the oyster treatment process as described in the request for verification, for any failure of the oyster treatment process to ~~reduce~~ meet the *Vibrio vulnificus* reduction standards in subsection 13675(a)(8), ~~to non-detectable levels,~~ or for any violation by the dealer of this article. ~~The department shall inform the person of any denial, revocation, or suspension in writing, stating the reasons for the denial, revocation, or suspension.~~

(h) The department shall inform the dealer of any denial, revocation, or suspension of any verification, in writing, stating the reasons for the denial, revocation, or suspension.

NOTE: Authority cited: ~~Section 15376, Government Code; and~~ Sections ~~100275,~~ 110065, 110105, 110430 ~~and~~, 112165(a), 131050, 131051, 131052, 131055, 131056, and 131200, Health and Safety Code. Reference: Sections 110435, 110545, 110660, 112165(c), 112195, 112200, ~~and~~ 113980, and 131071, Health and Safety Code.

REPEAL

DHH-06-006
Raw Gulf Oyster

U.S. Food and Drug Administration Bacteriological Analytical Manual, 8th Edition, 1995, pages 9.01-9.27