

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

§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 113895.
- (2) "FDA" means the United States Food and Drug Administration.
- (3) "Gulf oyster" means any oyster harvested from the states of Alabama, Florida, Louisiana, Mississippi, or Texas.
- (4) "Half-shell oyster" means any oyster from which one shell has been removed.
- (5) "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.
- (6) "Offers" means making raw oysters available to any person, whether the raw oysters are subject to purchase, exchange, or transfer, or are provided without charge.
- (7) "Orders" means requesting or selecting raw oysters for consumption on the premises of a retail food facility, or requesting or selecting raw oysters for consumption off the premises.
- (8) "Oyster treatment process" means a process that has been determined by the state shellfish control authority having jurisdiction, the FDA, or a recognized process authority to consistently reduce the level of *Vibrio vulnificus* to 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 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 Section 113895 of the Health and Safety Code and "food facility" as defined in Section 113789 of the Health and Safety Code.
- (11) "Shellfish Control Authority" means the State, or other regulatory authority, or its designated agents responsible for the enforcement of laws or regulations governing shellfish growing and harvesting areas, shellfish handling facilities and dealer activities including harvesting, transporting, storing, handling, processing, packing, and repacking of shellfish.
- (12) "Shellstock oyster" means any oyster in both shells.
- (13) "Shucked oyster" means any oyster from which both shells have been removed and which has been packed in a container by a dealer.
- (14) "Tent cards" means free-standing print displays or a printed display in a supporting stand designed for placement on dining tables or food service counters.
- (b) Every retail food facility that offers raw Gulf oysters shall provide a written warning to any person who orders raw oysters, as provided in this section.
- (1) The written warning shall be worded in English and Spanish as follows:

WARNING

THIS FACILITY OFFERS RAW OYSTERS FROM THE GULF OF MEXICO. EATING THESE OYSTERS MAY CAUSE SEVERE ILLNESS AND EVEN DEATH IN PERSONS WHO HAVE LIVER DISEASE (FOR EXAMPLE ALCOHOLIC CIRRHOSIS), CANCER OR OTHER CHRONIC ILLNESSES THAT WEAKEN THE IMMUNE SYSTEM. If you eat raw oysters and become ill, you should seek immediate medical attention. If you are unsure if you are at risk, you should consult your physician.

AVISO IMPORTANTE

ESTA FACILIDAD OFRECE OSTRAS CRUDAS DEL GOLFO DE MEXICO. A COMER ESTAS OSTRAS CRUDAS PUEDEN CAUSAR UNA ENFERMEDAD GRAVE Y HASTA LA MUERTA EN LAS PERSONAS QUE PADECEN DE ENFERMEDADES DEL HIGADO (POR EJEMPLO, CIRROSIS ALCOHOLICA), CANCER U OTRAS ENFERMEDADES CRONICAS QUE DEBILITAN EL SISTEMA INMUNOLOGICO. Si usted come ostras crudas y se enferma, debe buscar atencion medica inmediatamente. Si usted cree estar en peligro, debe consultar a un medico.

- (2) Where raw oysters are purchased by a consumer over a counter, or where they are

offered for sale by a sign, tag, or menu board, the sign bearing the warning set forth in subsection (b)(1) shall be prominently placed so that it is likely to be read by consumers prior to ordering raw oysters.

The warning signs shall meet the following specifications:

- (A) Be square in shape and no smaller than 10 inches on a side (100 square inches) or be rectangular in shape and no smaller than 11 inches high by 8.5 inches wide (93.5 square inches).
 - (B) Be printed in black ink on a white background, dark blue ink on a yellow background or other ink that is of high contrast from the color of the background material.
 - (C) At least 1/3" space shall be maintained around the notice.
 - (D) The word "Warning" and the words "Aviso Importante" shall be in all bold, upper case letters and underlined and be no smaller than 35 point type face.
 - (E) The first two sentences of the English and the Spanish version shall be in bold letters and be no smaller than 30 point type face. The remaining sentences of the English and the Spanish version shall be no smaller than 25 point type face.
- (3) Where raw oysters are ordered directly from a server, at a dining table, or where a warning sign posted pursuant to subsection (b)(2) is not clearly legible from any location where the consumer orders raw oysters, the warnings shall be printed on all menus in which raw oysters are listed, or on tent cards located on each dining table. For menus, the warning may be shortened to contain the headers and the first two sentences of the English and Spanish statements as set forth in subsection (b)(1) and shall be prominently placed on the menu so that it is likely to be read by consumers prior to ordering raw oysters. Tent cards shall contain the complete warning statements as set forth in subsection (b)(1) and be prominently placed on the dining tables so that they are likely to be read by consumers prior to ordering raw oysters. Both menu warning statements and tent card warning statements shall meet the following specifications:
- (A) Be printed in black ink on a white background, dark blue ink on a yellow Background or other ink that is of high contrast from the color of the background material.
 - (B) The word "Warning" and the words "Aviso Importante" shall be in all bold, upper case letters and underlined.
- (4) Menu warning statements shall meet the following additional specifications:

(A) Be no smaller than 10 point type face.

(B) Be enclosed by a box rule with no less than 1/8" of space around the notice.

(5) Tent card warning statements shall meet the following additional specifications:

(A) Be square in shape and no smaller than 4 inches on a side (16 square inches) or be rectangular in shape and no smaller than 3 inches high by 5 inches wide (15 square inches).

(B) The word "Warning" and the words "Aviso Importante" and the first two sentences of the English and Spanish version shall be in no smaller than 12 point medium or bold type face, and the remaining sentences shall be no smaller than 10 point type face.

(C) Be enclosed by a box rule with no less than 1/8" of space around the notice.

(c) Every dealer or retail food facility that offers raw oysters from any source shall do all of the following:

(1) Refuse to accept any container of raw shellstock oysters, half-shell oysters, or shucked oysters, if the container does not have a tag or label affixed that prominently and clearly bears the statement, "Harvested in _____", "Product of _____", or words of similar meaning (to be filled in with the name of the state or foreign country in which the raw oysters were harvested). For containers of raw oysters that have any oyster harvested from a state bordering on the Gulf of Mexico, this paragraph is satisfied when the container bears a tag or label affixed that prominently and clearly bears the statement "Harvested from the Gulf of Mexico", or "Product of the Gulf of Mexico".

(2) Refuse to accept raw shellstock oysters unless each container contains a tag or label that prominently and clearly bears all of the following:

(A) The harvest date of the oysters.

(B) The bed name or lease number assigned by the shellfish control authority to the harvest area.

(C) The state abbreviation and certification number assigned by the shellfish control authority to the harvester, or original dealer.

(3) Refuse to accept raw shucked oysters unless each container of oysters bears a label that prominently and clearly states all the following:

- (A) The sell-by-date, date-shucked, date-packed, or similar date of the shucked oysters.
 - (B) The state abbreviation and certification number assigned by the shellfish control authority of the state or foreign country to the harvester or original dealer.
 - (C) The harvest date of raw Gulf oysters. This requirement is satisfied when each shipment of raw oysters is accompanied by an invoice that specifies the harvest date of the oysters.
 - (D) That raw Gulf oysters, which have not been subjected to an oyster treatment process, be cooked before eating.
- (4) Refuse to accept any container of raw half-shell oysters unless each container of oysters bears a tag or label that prominently and clearly states the information required in subparagraphs (c)(3)(A), (B), and (C).
- (5) Refuse to accept any container of raw shellstock, half-shell, or shucked Gulf oysters harvested during April through October, and such oysters shall be deemed adulterated, unless:
- (A) The oysters have been subjected to an oyster treatment process and are prominently and clearly tagged or otherwise labeled with the information required by subsection (i); and
 - (B) The dealer or retail food facility has on file a current copy of the letter from the department verifying the use of an oyster treatment process in accordance with subsection (h).
- (d) Warnings under subsection (b) are not required for raw shellstock, half-shell or shucked Gulf oysters whenever the retailer has received a copy of a current verification letter from the dealer pursuant to subsection (h) and tags or labels as required by subsection (i) demonstrating that the oysters have been subjected to an oyster treatment process.
- (e) In order to be eligible to receive verification by the department that oysters supplied by the dealer are subjected to an oyster treatment process, a dealer shall submit a written request for verification pursuant to Section 13676. A verification issued by the department shall be valid for two years from the date of issue unless revoked or suspended.
- (f) A dealer who has received a verification pursuant to Section 13676 shall notify the department in writing prior to making any changes to the oyster treatment process, or

any changes to the Hazard Analysis and Critical Control Point (HACCP) plan required by Title 21, Code of Federal regulations, Part 123.

- (g) A dealer who has received a verification pursuant to Section 13676 shall notify the department, within seven days, of any new information known to the dealer pertaining to the effectiveness of the oyster treatment process.
- (h) A dealer who has received a verification pursuant to Section 13676 shall provide a copy of the letter from the department granting the current verification to every dealer and retail food facility in California to whom the dealer sells or provides shellstock, halfshell, or shucked raw Gulf oysters. Every dealer and retail food facility that offers shellstock, half-shell, or shucked raw Gulf oysters for which a verification pursuant to Section 13676 has been granted, shall retain and make available for inspection by the department and local health agencies a copy of the current verification letter provided by the dealer. A retail food facility shall retain the copy of the verification for one year after the date that the verification expires.
- (i) A dealer who has received a verification pursuant to Section 13676 shall affix to each container of raw Gulf oysters 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 110065, 110105, 110430, 112165, 113707, 131050, 131051, 131052, 131055, 131056, and 131200, Health and Safety Code. Reference: Sections, 110175, 110545, 110560, 110565, 110660, 110705, 112195, 112200, 113980, 114029, 114039, 114039.1, 114039.2, 114039.3, and 114039.4, Health and Safety Code.

§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:
- (1) The name and address of the dealer;
 - (2) A copy of the shellfish certificate or license issued by the Shellfish Control Authority having jurisdiction;
 - (3) A description of the process used to treat the oysters and the procedures used to ensure that oysters harvested during April through October and shipped to California are subjected to the treatment.
 - (4) A report by the Shellfish Control Authority or a recognized process authority, accompanied by the concurrence of the FDA verifying that the process used consistently reduces the level of *Vibrio vulnificus* level to less than 30 MPN per gram and achieves a minimum 3.52 log reduction in processed oysters.
 - (5) Signature, under penalty of perjury, of the individual requesting verification attesting to the accuracy of the information provided in the request for verification.
- (b) Requests for verification shall be deemed complete when the information specified in subsection (a) has been received in writing by the department. Initial requests for verification may be submitted at any time to the department. Requests for renewals shall be submitted to the department no later than 60 days prior to the expiration date. Requests for verification shall state whether the dealer is requesting an initial verification or renewal of an existing verification.
- (c) The department shall notify the dealer in writing within 15 days of receipt of a request for verification of one of the following:
- (1) The request for verification is complete and shall be evaluated by the department, or
 - (2) The request for verification is incomplete and not accepted for evaluation. The department's written notification shall describe the specific information or documentation that is deficient.
- (d) Within 60 days of the receipt of a complete request for verification, the department

shall notify the dealer of one of the following:

- (1) That the oyster treatment process has been verified, or
 - (2) That the request has been reviewed and denied for failure to establish that each oyster harvested during April through October and sold or distributed in California will be subjected to an oyster treatment process. The department shall provide a written description in the notification of the basis for the denial.
- (e) Written notification by the department to dealers requesting verification shall be deemed to occur on the date that the notification is postmarked.
- (f) The department shall deem a request for verification abandoned by a dealer requesting verification who fails to respond or to supply information or documents within 30 days of notification by the department.
- (g) The department may revoke or suspend a verification granted pursuant to Subsection 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 meet the *Vibrio vulnificus* reduction standards in subsection 13675(a)(8), or for any violation by the dealer of this article.
- (h) The department shall inform the person of any denial, revocation, or suspension of any verification, in writing, stating the reasons for the denial, revocation, or suspension.

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