

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



TO: California Food Retailers

SUBJECT: Limiting the Sale of Raw Oysters Harvested from the Gulf of Mexico California Code of Regulations (CCR) Title 17, Sections 13675 and 13676

Each year, Californians become seriously ill and die after consuming raw oysters harvested from the states bordering the Gulf of Mexico (Alabama, Florida, Louisiana, Mississippi, and Texas), contaminated with the pathogen *Vibrio vulnificus* (V. vulnificus). *V. vulnificus* bacteria are naturally present in marine environments. But, the bacteria are at some of their highest levels in Gulf Coast waters and oysters, especially during the warm summer months.

Since 1983, there have been 75 illnesses resulting in 49 deaths reported in California that have been associated with the consumption of raw oysters containing *V. vulnificus*. Persons with certain chronic diseases, especially those associated with liver disease are at high-risk. Nationally, over 50 percent of high-risk individuals who become ill, die. The Department of Public Health (CDPH), formerly known as the Department of Health Services (DHS), amended CCR, Title 17, Section 13675 to prevent *V. vulnificus* illnesses and deaths associated with the consumption of raw Gulf oysters. **The most significant revision restricts the sale of raw oysters harvested from the Gulf of Mexico during April 1 through October 31, unless the oysters are treated with a scientifically validated process to reduce** *V. vulnificus* **to non-detectable levels. Raw Gulf oysters received during April through October that have not been processed to reduce V. vulnificus to non-detectable levels are considered adulterated.**

Additional requirements of Title 17, Section 13675 requires retailers to:

1. Provide a written warning, in English <u>and</u> Spanish, to any person who orders raw Gulf oysters 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. Amended Regulation: California Code of Regulations (CCR) Title 17, Section 13675 Limiting the Sale of Raw Gulf Coast Oysters in California

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."

Note: Retailers are exempted from these warning requirements when they provide Gulf oysters that have been treated to reduce V. vulnificus to non-detectable levels. However, retailers are reminded that the warnings are required during November through March when raw, untreated Gulf oysters are received and sold by retailers.

- 2. Only accept raw shellfish that bears a label or tag that declares a statement of origin (e.g. "Harvested in (State)"). A new provision allows Gulf Coast oyster dealers to place a geographical statement of origin (e.g. "Product of the Gulf of Mexico").
- 3. Only accept raw shellstock that bears a label or tag stating 1) the date of harvest, 2) the harvest area, and 3) certificate number established by the state shellfish control authority.
- 4. Only accept shucked and half-shell oysters that bear a label or tag stating 1) the sellby-date, date-shucked, date-packed or other similar date; and 2) the certificate number of the harvester or dealer. A new provision requires containers of raw shucked or half-shell Gulf oysters to bear a label declaring the harvest date. However, this requirement is satisfied if the harvest date is supplied on an invoice accompanying each shipment.

New provisions require retailers to:

- Only accept raw, fresh-shucked oysters that have a tag or label stating they be cooked before eating.
- Refuse to accept raw, fresh or frozen, shellstock, half-shell or shucked Gulf Coast oysters harvested from April 1 through October 31 unless:
 - (a) The oysters have been treated by an approved method shown to reduce the level of *V. Vulnificus* to "non-detectable".
 - (b) Their container bears a label or tag that clearly and prominently states "PROCESSED TO REDUCE VIBRIO VULNIFICUS TO NON-DETECTABLE LEVELS", and

Amended Regulation: California Code of Regulations (CCR) Title 17, Section 13675 Limiting the Sale of Raw Gulf Coast Oysters in California

(c) The retailer and dealer have on-site and available for inspection a copy of the current letter of verification of the process used to reduce *V. Vulnificus* to non-detectable levels issued by the Department of Public Health to the dealer.

New provisions also allow dealers who process Gulf oysters with an opportunity to receive verification by the department that the oysters supplied by the dealer are subjected to an oyster treatment process. A dealer who has received a letter of verification is required to provide a copy of the letter of verification to every dealer and retail food facility in California to whom the dealer provides raw Gulf Coast Oysters that have been treated to reduce V. vulnificus to non-detectable levels.

Dealers that have received verification, shall affix to each container of raw Gulf Coast oysters processed to reduce V. vulnificus to non-detectable levels, a tag or label that clearly and prominently bears the statement "PROCESSED TO REDUCE VIBRIO VULNIFICUS TO NON-DETECTABLE LEVELS".

CCR, Title 17, Section 13676 has been added to provide the administrative procedures and timelines for verification requests. Most of these procedures were previously provided in Section 13576 and have been incorporated in Section 13676 for clarity.

CDPH is working with retailers and local health departments to implement the requirements of Title 17, Section 13675. If you have any questions regarding this notice contact the Department of Public Health, Food and Drug Branch (FDB) at (916) 650-6500 or the FDB web page at <u>www.cdph.ca.gov</u>.