

To Retail Food Regulatory Agencies:

We are providing the following information to you in advance of its delivery to the retail food trade organizations and asking your assistance in advising food establishments that raw oysters labeled “For Cooking Only” should not be sold or served to consumers in the raw form. FDA expects this “For Cooking Only” labeling as a control for the reduction of risk associated with *Vibrio parahaemolyticus* in oysters to be a temporary measure.

We are asking your assistance to help provide the attached information to retailers and restaurateurs who serve or sell raw oysters. If possible, please forward this advice to your organization’s members and to your state affiliate organizations as well. Certain states are requiring some shipments of oysters be labeled “For Cooking Only” as part of their *Vibrio parahaemolyticus* Control Plan under the National Shellfish Sanitation Program (NSSP).

This attachment explains what that means and how these oysters should be used. Thank you for helping us get this public health message out to food establishments that serve or sell this product.

If you have further questions, please contact your regulatory agency or an FDA Regional Retail Food Specialist.

August 6, 2008

FDA Advice to Retail and Foodservice Operations on Raw Oysters Shipped With “For Cooking Only” Label As Part Of A *Vibrio parahaemolyticus* Control Plan

FDA is advising retail and foodservice operations to be aware that raw oysters shipped in containers bearing a “For Cooking Only” label may have a greater likelihood of containing harmful levels of the *Vibrio parahaemolyticus* (*Vp*) bacterium, which may cause illness, than do raw oysters not labeled in this manner.

Retail and foodservice operations should not purchase containers or packages of raw oysters that bear the “For Cooking Only” label unless the operator intends to fully cook the product before offering it for sale or service to the consumer.

The label is the result of new National Shellfish Sanitation Program provisions that call for oyster dealers to use the new label if harvesting conditions do not meet specific criteria for reduced risk of *Vp* contamination.

In addition to thoroughly cooking oysters that have the “For Cooking Only” label, food establishments that receive these oysters should take extra precaution to prevent cross-contamination of other foods and surfaces.

Molluscan shellfish, such as raw oysters, should be obtained only from sources listed on the [Interstate Certified Shellfish Shippers List](#). This helps ensure that they are harvested and shipped in accordance with the [National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish](#). [Note: direct web link will be established when click on title of documents]

FDA is advising state and local regulatory officials to encourage food establishments receiving raw oysters bearing a “For Cooking Only” label to ensure that the product is being fully cooked before sale or service to the consumer. Food establishments should be made aware that merely advising consumers to cook these labeled oysters at home or advising consumers that they may be at higher risk of a foodborne illness if they order these oysters raw from a menu may not provide an adequate level of protection from foodborne illness.

While the FDA Food Code does not contain provisions that explicitly prohibit the sale of the labeled oysters to consumers in the raw form, retailers should be aware of the hazard and should understand that many consumers may assume that they can consume the oysters raw, just as they have with oysters they purchased in the past.

Background

Over the past several years, FDA has worked closely with the Interstate Shellfish Sanitation Conference (ISSC) to identify and implement effective strategies for the reduction illness from consumption of raw oysters contaminated with harmful levels of *Vibrio parahaemolyticus* (*Vp*).

At its 2007 Biennial Meeting, the ISSC adopted a *Vibrio parahaemolyticus* Control Plan for incorporation into the Model Ordinance of the National Shellfish Sanitation Program. The *Vp* Control Plan outlines measures to be taken by states to evaluate and control the risk of *Vp* illness associated with consumption of raw oysters harvested from their state. In part, the Control Plan recognized that, in the absence of control measures that adequately control for *Vp* prior to reaching retail outlets, State regulatory agencies could allow raw oysters to be sold in interstate commerce provided those oysters were sold in containers that bore the label “For Cooking Only.”

A number of states, including several major oyster producers, chose to accept “For Cooking Only” labeling as an appropriate control measure for the oyster industry in their state. FDA and the ISSC are reassessing the appropriateness of such controls. In the meantime, it is likely that containers and packages of raw oysters, both as shellstock and shucked product, will enter the marketplace bearing labels that read “For Cooking Only.” In light of this, FDA is providing the aforementioned advice to retail and foodservice operations that purchase oysters for sale or service.

Additional Points to Consider

The 2005 FDA Food Code currently recognizes that food establishments may serve undercooked animal foods to a consumer upon his or her specific request, if the consumer is properly advised of the hazards associated with eating undercooked animal foods. Many consumers and food establishments exercise this “consumer advisory” option with oysters.

Food establishments need to recognize that purchasing oysters that were shipped in containers bearing a label “For Cooking Only” and offering them for sale in the raw form may put their customers at risk for foodborne illness. Based on where and when they were harvested, there may be a greater likelihood that these oysters will contain *Vp* at levels that, if not fully cooked, may result in foodborne illness and therefore the normal public-health protections provided by the National Shellfish Sanitation Program cannot be assured.

For oysters, the term “fully cooked” means that the product is allowed to reach an internal temperature of at least 145°F for 15 or more seconds.

The FDA Food Code contains additional recommendations for safe food handling practices in retail and foodservice operations. The Food Code also contains provisions for ensuring that molluscan shellfish is obtained from safe sources and requirements for food establishment operators with respect to maintaining the tags and labels that shellstock and shucked shellfish are required to bear.

The FDA Food Code and the state and local codes modeled after it include requirements directed at preventing cross-contamination between raw animal foods and ready-to-eat foods and surfaces that may contact ready-to-eat foods. Proper separation of raw and ready-to-eat foods and effective cleaning and sanitizing of surfaces between uses are among the most important of these provisions. Strict adherence to these preventative requirements becomes even more critical when preparing and working with raw oysters that may contain elevated levels of *Vp*.

About *Vibrio parahaemolyticus*

Vibrio parahaemolyticus is a marine bacterium that occurs naturally in filter-feeding molluscan shellfish, like oysters. Some strains or types of *V. parahaemolyticus* are pathogenic and can cause food poisoning in people who eat shellfish containing these strains. Because *V. parahaemolyticus* is destroyed by thorough cooking, the disease is generally associated with eating raw shellfish, or cooked seafood products cross-contaminated by raw shellfish. *V. parahaemolyticus* was first implicated in an outbreak of food poisoning in Japan, in 1950, and has been associated with sporadic cases and outbreaks (multiple cases) of illness in the United States since 1969.