Risk per Serving Calculation

General Information Regarding Risk per Serving Input Data:

Under National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) Chapter II @.05 there are three risk per serving standards based on water temperature. When water temperatures are >80°F the risk per serving standard is <3 illnesses per 100,000 servings. When water temperatures are >75 but ≤80°F the risk per serving standard is <2.5 illnesses per 100,000 servings. When water temperatures are >70°F but ≤75°F the risk per serving standard is 1.75 illnesses per 100,000 servings.

FDA and the Interstate Shellfish Sanitation Conference (ISSC) have used the assumptions and methods outlined in the *Vibrio vulnificus* Risk Assessment (VVRA) to estimate the size and number of raw oyster servings consumed by individuals at risk for *Vv* primary septicemia. These methods and assumptions are also the basis of the *Vv* Risk Calculator and they will be used by FDA to determine risk per serving as shown below. The fishery statistics collected by the National Marine Fishery Service (NMFS) will be used to determine monthly oyster landings for each state. An ISSC sanctioned study indicated that 50 percent of oysters harvested over all Gulf states are consumed raw. That study is the basis of the assumption in the VVRA that 50 percent of oysters produced from each state are consumed raw during each month. An oyster consumption survey conducted in Florida was used to determine the distribution of the number of raw oysters consumed during a meal. The mean of this distribution was 13 oysters per serving and this was used in the VVRA. The survey did not address the weight of an oyster serving. The weight of an oyster serving was instead obtained by a U.S. market survey of raw oysters conducted by FDA and ISSC in 1998-1999. As part of the sample preparation the number of oysters and their corresponding weight were recorded. These data indicated that the average weight of an oyster was approximately 15 grams and the mean weight of a meal consisting of 13 oysters was assumed to be 196 grams.

A number of underlying chronic illnesses predispose individuals to primary septicemia. The Centers for Disease Control and Prevention (CDC) statistics on the incidence of the chronic illnesses indicate cumulatively that approximately 7 percent of the U.S. population is afflicted with one or more of these predisposing conditions. Thus the VVRA assumed that 7 percent of the population was at risk for *Vv* septicemia. In the absence of data on raw oyster consumption rates among the at risk population, it was also assumed that they consume raw oysters at the same rate as the general population.

Calculating Meals Consumed by At-Risk Population:

The following calculation was used to determine the number of raw oyster servings consumed by individuals at-risk for *Vv* primary septicemia. This formula is used for calculating the number of servings for states individually and states collectively.

Number of meals = (Pounds produced) X (454 grams/pound) X (1 meal/196 grams) X (0.5 fraction consumed raw) X (.07 fraction consumed by at-risk individuals)

Example: (367,260 lbs.) X (454) ÷ (196) X (.5) X (.07) = 29,774 meals

Calculating Risk per Serving:

Example 1 and 2 below use the above example of 29,774 raw meals consumed by at-risk individuals:

Example 1:

> Two illnesses are attributed to harvest during the high risk period of June – September when water temperatures were >80°F. Therefore the illness rate is two illnesses per 29,774 servings. This equates to a risk per serving of 6.7 illnesses per 100,000 meals. In this case the state fails to meet the risk per serving standard of <3 illness/100,000 servings.

Example 2:

> One illness is attributed to harvest during the high risk period of June – September when water temperatures were >80°F. Therefore the illness rate is one illness per 29,774 servings. This equates to a risk per serving of 3.3 illnesses per 100,000 meals. Although the calculated risk per serving is greater than the NSSP standard of <3/100,000, the state will not be deemed in non-compliance because compliance will not be assessed if no more than one illness occurs during the risk period being considered.

The example below uses 521,000 lbs. of oyster meat which equates to 42,238 raw meals consumed by at-risk individuals:

Example 3:

> One illness is attributed to harvest during the moderate risk period of May and October when water temperatures were >75 but ≤80°F. Therefore, the illness rate is one illness per 42,238 servings. This equates to a risk per serving of 2.4 illnesses per 100,000 meals. In this case the state complies with the NSSP risk per serving standard of ≤2.5 illness/100,000 servings.

Case counting:

- If a single *Vv* control plan state (currently Texas, Louisiana, Florida, Mississippi, Alabama, Virginia) is identified as the source state then case attribution is assigned to that state
- If a *Vv* control plan state and a non-*Vv* control plan state are identified as source states then case attribution is assigned to the *Vv* control plan state
- If multiple *Vv* control plan states are among the identified source states then case attribution is fractionally assigned to each *Vv* control plan state
- If the source state(s) is unknown, no case attribution is assigned
- If only a non- *Vv* control plan state(s) is identified as the source state(s) then no case attribution is assigned to a *Vv* control plan state.