Interpretive Summary:

Draft Risk Assessment on the Public Health Impact of *Vibrio parahaemolyticus* in Raw Molluscan Shellfish

Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

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PREFACE

In response to the 1997 and 1998 outbreaks of *V. parahaemolyticus* infections in the United States, the Food and Drug Administration (FDA) conducted a risk assessment to characterize the public health impact associated with consumption of raw oysters harboring pathogenic *V. parahaemolyticus*. This risk assessment focused specifically on oysters, because this was the food predominantly linked to the outbreaks. The risk assessment structures our knowledge of *V. parahaemolyticus* in a systematic manner, and includes sophisticated, mathematical models developed to estimate exposure to this microorganism and the dose-response relationships between the consumer and *V. parahaemolyticus*.

This interpretive summary is a non-technical version of the formal risk assessment document. The formal risk assessment document is designed to communicate the details of how the analysis was carried out. It frequently requires the use of technical terms and advanced statistical concepts that are sometimes not familiar to non-scientists. This interpretive summary includes the essential elements of the risk assessment in a manner that can be understood by non-scientists. It states simply why the risk assessment was conducted, what was required of the risk assessment team and what was done in response, what the results were, and what these results signify. It is recommended that those who wish to do an in depth evaluation of the work read the complete risk assessment document. The entire assessment document may be found on the FDA/CFSAN website: http://www.foodsafety.gov/~dms/fs-toc.html.

We have attempted to seek the best scientific information available. However, to ensure that we have both identified all key data sources and submitted the assessment to a rigorous peer review, we are releasing the assessment in draft form. A comment period has been established during which we will be actively seeking comments, suggestions, and additional data sources. Written comments should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 within 60 days after publication of the document. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments must be identified with the Federal Register Docket No. 99N-1075. The information acquired during the comment period will be reviewed and used, as appropriate, to further enhance the risk assessment and decrease uncertainty to the greatest degree possible. As stated in the Federal Register, Docket No. 99N-1075, the preliminary results of the draft *V. parahaemolyticus* risk assessment will be presented at a public meeting during the comment period.

INTRODUCTION

V. 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. Outbreaks in the U.S. had not been recorded since 1984. The outbreaks in 1997 and 1998 renewed concern for this pathogen as a serious foodborne threat to public health. In two of the 1998 outbreaks a serotype previously reported only in Asia, O3:K6, emerged as a principal cause of illness in the United States for the first time. The outbreaks also introduced uncertainty about the effectiveness of current criteria for closing and reopening shellfish waters to harvesting, and about previous FDA guidance indicating that no more than 10,000 *V. parahaemolyticus* per gram should be present in shellfish. The levels of *V. parahaemolyticus* found in oysters from the harvest sites implicated during the 1997 and 1998 outbreaks suggested that the number of pathogenic cells required to cause illness is less than previously believed. Also, accounts from some patients indicated that illness might have resulted from eating as little as a single infected oyster.

RISK ASSESSMENT: SCOPE AND GENERAL APPROACH

A risk assessment is the evaluation of the current state of knowledge about a hazard and it makes estimates of the probability that harm will occur after exposure to the hazard. It can include either a qualitative review of published information on the hazard or a quantitative assessment of risk. This risk assessment contains a quantitative model of the *V. parahaemolyticus*-oyster problem and provides an updated evaluation of the available scientific data concerning the public health impact of consuming raw oysters containing pathogenic *V. parahaemolyticus*. Specific information included the levels of *V. parahaemolyticus* in oysters at harvest and consumption, environmental factors affecting *V. parahaemolyticus* levels in oysters, dose response and patient susceptibility relationships, and the influence of post-harvesting practices on *V. parahaemolyticus* growth. The model simulates the processes of oyster harvest and consumption and can be used to predict the number of expected cases of *V. parahaemolyticus*. Each step in the risk assessment process is modeled separately and the results are put together in an overall model. In many places, the model uses distributions of data rather than single point estimates as both inputs and outputs. This technique allows the model to simulate the variability and uncertainty in real world data more accurately than would be possible with point estimates.

In general, the risk assessment process includes four steps: 1) Hazard Identification, which identifies a potential hazard, 2) Exposure Assessment, which characterizes the level of exposure of people to the hazard, 3) Hazard Characterization/Dose-Response, which provides information needed to relate exposure to the hazard to the occurrence and severity of disease, and 4) Risk Characterization, which characterizes the impact of the hazard on public health, given the hazard characterization data and the size of the consuming population. This risk assessment is structured according to these four steps. The steps are further divided between three modules that reflect the chain of events from oyster harvest to consumption: Harvest, Post Harvest, and Public Health. In addition, because *V. parahaemolyticus* levels may be affected by climate and by region-specific oyster harvesting practices, the quantitative modeling was done separately for each season and for five separate geographic regions (Northeast Atlantic, Mid-Atlantic, Pacific Northwest, Louisiana Gulf Coast, and the remaining Gulf Coast).

HAZARD IDENTIFICATON

The hazard considered by this risk assessment is *V. parahaemolyticus*. As noted above, *V. parahaemolyticus* occurs naturally in marine environments and therefore can be present in many fishery products, including molluscan shellfish. *V. parahaemolyticus* infections in humans result from consumption of raw shellfish containing pathogenic *V. parahaemolyticus* strains; proper cooking destroys the *V. parahaemolyticus* bacteria. The most common clinical manifestation of infection with pathogenic *V. parahaemolyticus* is gastroenteritis, characterized by diarrhea, vomiting, and abdominal cramps. Gastroenteritis is usually a self-limited illness of moderate severity and short duration. However, on rare occasions, in a small percentage of cases, *V. parahaemolyticus* infection can result in life-threatening septicemia, in which pathogenic microorganisms or their toxins are found in the blood. This condition is most likely to occur in patients with underlying medical conditions such as cancer, liver disease, diabetes, kidney disease, and heart disease, as well as people who use antacids or have had gastric surgery.

Sporadic (isolated) cases of *V. parahaemolyticus* infections are primarily reported by the Gulf Coast states. Sporadic cases occur throughout the year, peaking in spring and summer. The Centers for Disease Control (CDC) estimates that the total number of foodborne *V. parahaemolyticus* cases in the United States for 1996, 1997, and 1998 were 2730, 8596, and 5525, respectively. These estimates include a projection on the part of CDC that due to under diagnosing and underreporting, the total number of cases is 20 times greater than the number of cases that are actually reported in each year.

Although *V. parahaemolyticus* infections have been linked to crayfish, shrimp, and crab consumption, the recent outbreaks in the United States and Canada were attributed predominantly to consumption of raw oysters. Food intake surveys indicate that raw shellfish is not a commonly consumed food in the U.S., with only about 10 to 20 percent of the population consuming raw shellfish at least once a year. Among raw shellfish consumers, a serving of raw oysters is eaten approximately once every six weeks, normally with a range of 6 to 24 oysters per serving.

Pathogenic strains of *V. parahaemolyticus* may have one or more distinctive traits compared with nonpathogenic *V. parahaemolyticus* strains, including the ability to produce thermostable direct hemolysin (TDH, a toxic substance that breaks down red blood cells). The vast majority of *V. parahaemolyticus* strains isolated from the stools of people with *V. parahaemolyticus* infections are TDH-positive, and recently improved methodology has enabled scientists to detect these strains in oysters when they are present in sufficient amounts. Other traits have also been linked to pathogenic strains, including the ability to invade the intestine, the ability to produce an enterotoxin (a toxin that causes diarrhea in animals), and the ability to produce urease, an enzyme that can help microorganisms survive the acidic conditions of the stomach. However, the role of the traits other than TDH in pathogenicity is still unclear.

EXPOSURE ASSESSMENT

The purpose of exposure assessment is to determine how likely it would be for consumers to ingest pathogenic *V. parahaemolyticus* by eating raw oysters, and the amount of pathogenic *V. parahaemolyticus* present when consumed. It characterizes the level of exposure to *V. parahaemolyticus.* Levels of *V. parahaemolyticus* in oysters were estimated at time of harvest, during post-harvest processing, and at the time of consumption.

Harvest

The harvest component of the exposure assessment identified factors that influence the presence of *V. parahaemolyticus* and quantified the levels in oysters harvested from different regions within the United States. The risk assessment identified and reviewed a number of important factors that can affect *V. parahaemolyticus* levels. For example, *V. parahaemolyticus* can appear in a shellfish-growing area when ships discharge contaminated ballast water or when birds and fish that carry *V. parahaemolyticus* enter shellfish areas in their natural movements.

Once present in the environment, *V. parahaemolyticus* levels can be affected by such factors as the amount of zooplankton in the shellfish growing area, the rate of tidal flushing, levels of dissolved oxygen in the water, the presence of pollutants, water temperatures and salinity levels. Oyster-specific factors, such as the physiology and health of the oyster, may also contribute to the ability of *V. parahaemolyticus* to infect and grow in the oysters. Toxins or other proteins produced by bacterial strains that infect oysters at the same time as *V. parahaemolyticus* may also affect the survival of the *V. parahaemolyticus*. Estimates from several studies suggest that the average percentage of pathogenic *V. parahaemolyticus* is higher on the West Coast (approximately 3%) than in other areas of the country (0.2 to 0.3%).

In summary, a review of published studies on *V. parahaemolyticus* suggests that a number of factors can affect the presence and growth of *V. parahaemolyticus* in oysters at the time of harvest. However, only water temperature and percent pathogenic *V. parahaemolyticus* were incorporated into the model because there was little published quantitative data available to introduce the other harvest-related factors. The model demonstrated that although both water temperature and salinity affect *V. parahaemolyticus* levels, salinity has a minor effect. Water temperature, on the other hand, has a major effect, with total *V. parahaemolyticus* levels increasing as water temperature increases. The model is constructed so that it reflects this relationship between *V. parahaemolyticus* levels and water temperature. Likewise, as noted above, the percentage of *V. parahaemolyticus* that is pathogenic varies from region to region in the U.S; the model also takes this variation into account. The final output of this component of the model is a set of regional and seasonal estimates of *V. parahaemolyticus* levels at time of harvest.

Post Harvest

After oysters are harvested, they go through a series of processing steps before consumption, including transportation, handling, processing, and distribution. The Post Harvest component of the Exposure Assessment describes the effect that handling practices have on *V. parahaemolyticus* levels. For example, after harvesting, oysters are generally stored unrefrigerated on the oyster boat for some period of time, ranging from a few hours to more than a half a day. A quantitative model was used to describe the growth of *V. parahaemolyticus* in the oysters during this unrefrigerated period, taking into account such factors as air temperature and length of the harvest day. Once the oysters are refrigerated (e.g., during transport or after arrival at wholesalers or restaurants), the rate of *V. parahaemolyticus* growth conditions change. Therefore *V. parahaemolyticus* growth under refrigeration was also modeled, this time by taking into account the length and efficiency of the cooling process, the fact that *V. parahaemolyticus* grows more slowly when refrigerated, and the fact that some *V. parahaemolyticus* cells will die during refrigeration. The overall output from the Post Harvest component of the exposure assessment is an estimate of *V. parahaemolyticus* levels at the time of consumption, given *V. parahaemolyticus* levels at harvest and changes in those levels after harvest.

The model developed for the Post Harvest Exposure Assessment was also used to test the effects of several interventions that have been proposed for decreasing growth or presence of *V. parahaemolyticus*. Proposed intervention measures include rapid cooling of oysters immediately after harvest, and mild heating (5 minutes at 50 °C) or freezing (35 days at –20 °C) of oysters. The resulting data were subsequently used to determine the effect of these measures on the probability of illness.

Consumption

The Harvest and Post Harvest components of the Exposure Assessment provided the estimates of the *V. parahaemolyticus* levels in oysters at the time of consumption. The final step in the Exposure Assessment is determining how much *V. parahaemolyticus* people are actually consuming, based on the number of oysters they eat and the weight of those oysters. Estimates of oyster consumption and oyster weight were modeled using data from food consumption surveys and oyster harvest statistics.

HAZARD CHARACTERIZATION/DOSE RESPONSE

A key part of modeling *V. parahaemolyticus* infections is describing the dose-response relationship, or the relationship between the amount of *V. parahaemolyticus* that people ingest and the likelihood that they will become ill. In general, dose-response models are based on observations of what dose levels caused illness in the past, either in well-controlled clinical studies or in disease outbreaks. Once a dose-response relationship for *V. parahaemolyticus* is defined, that relationship can be used to predict the number of illnesses that will result from ingesting various amounts of *V. parahaemolyticus.*

To develop a quantitative dose-response model, this risk assessment relied on epidemiologically based estimates of illness rates and human clinical trial data from studies performed prior to 1974, in which human volunteers received specific doses of *V. parahaemolyticus* with concurrent antacid administration (which eliminates the protective effect of stomach acid). Analysis of the data indicated that the presence of antacid may have had a substantial effect on dose-response. Consequently, the dose-response model was modified using epidemiological data to adjust for the fact that the clinical trial participants were fed *V. parahaemolyticus* doses with antacids.

The risk assessment also reviewed a variety of human and animal studies of infection with *V. parahaemolyticus* (or with other *Vibrio* species that can serve as surrogates for *V. parahaemolyticus* infection). The review suggests that a number of factors can affect the infectious *Vibrio* dose. These factors include route of exposure (e.g., by mouth or by injection), food matrix factors (e.g., fat content), bacterial virulence factors (e.g., TDH production, enterotoxin production, invasion, presence of iron-limiting conditions), and host factors (immune status of the host).

Another aspect of dose-response relationships is the severity of infection, i.e., will the patient just develop gastroenteritis or will the patient go on to develop septicemia. People with underlying medical conditions (e.g., the immunocompromised population) are more likely to develop septicemia than people without underlying conditions. Using CDC data, the risk assessment model predicts the likelihood that a *V. parahaemolyticus* patient will develop septicemia, and estimates the expected number of cases of septicemia.

RISK CHARACTERIZATION

Risk characterization combines the results of the exposure assessment and the hazard characterization to produce an estimate of the likelihood of adverse health effects associated with *V. parahaemolyticus*. It also provides estimates of the variability and uncertainty associated with the predictions of relative risk and the contributing factors. This information is critical to the correct interpretation of the results of a risk assessment. In a quantitative risk assessment, such as this, the risk characterization is developed using computer simulation modeling techniques and then interpreted in relation to the scientific data and expert scientific judgement.

The risk characterization results are in the form of distributions, or ranges of possible cases. For simplicity's sake, this summary presents the mean of these ranges; i.e., the mean number of predicted cases. (A more detailed description of the distributions can be found in the technical document.) For the Gulf Coast, the model predicts a mean of 25 cases of *V. parahaemolyticus* infections in winter, 1,200 in spring, 3,000 in summer, and 400 in fall. For the Pacific Northwest, the model predicts a mean of 15 cases in spring and 50 in summer; for the Mid-Atlantic, 10 cases in spring and 12 in summer; and for the North Atlantic, 12 cases in spring, 30 in summer and 7 in fall. The predicted number of cases in the North and Mid-Atlantic is low even for the summer, because the harvest sizes and water temperatures in these regions are relatively low compared with other regions. In fact, because the number of expected cases was so low, exact estimates could not be made for the Mid-Atlantic fall and winter and the North Atlantic winter harvests. The model also predicts that an average of six septicemia cases per year will occur in the U.S.

In addition to predicting number of illnesses, the model also tested the effectiveness of proposed intervention measures, such as rapid cooling of oysters after harvest, mild heat treatment (5 min at 50° C), and freezing at -40° C. The model predicts that these measures would be very effective in reducing the risk of *V. parahaemolyticus*-related infection (Figure 1). For example, for the Gulf Coast summer, simulated rapid cooling reduced the mean number of estimated illnesses from 3000 to approximately 300, and freezing reduced the estimated mean to 125. Mild heating was the most effective intervention, reducing the mean number of estimated cases per year to less than 20. The model predicted that interventions would be effective for all seasons and regions, with the most pronounced effects seen for regions and seasons with higher baseline risk.

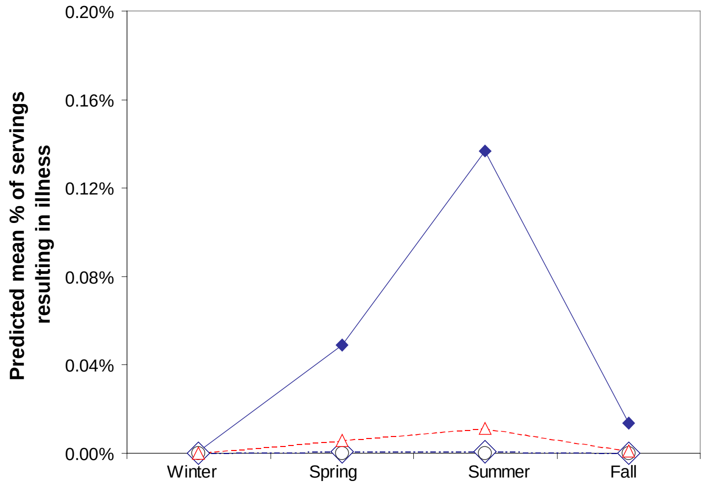

Figure 1. Effect of intervention measures on reducing the predicted risk of *V. parahaemolyticus* illnesses from Gulf Coast summer harvests: no mitigation (♦); freezing (◊); heat treatment (○); rapid cooling (△).

The model can also be used to evaluate which environmental or processing factors have the strongest influence on probability of illness. An example of this type of evaluation (sensitivity analysis) is shown in Figure 2. In this graph, a tornado plot, factors are ranked by the magnitude of their effects (whether positive or negative). For example, Figure 2 shows that the most important factor in determining the risk of *V. parahaemolyticus*-associated illness per serving for Gulf Coast summer harvests is the level of total (pathogenic and nonpathogenic) *V. parahaemolyticus* in oysters at time of harvest. However, the model is based on a correlation between total and pathogenic *V. parahaemolyticus* levels at time of harvest and assumes that pathogenic strains of *V. parahaemolyticus* grow at the same rate as non-pathogenic strains. Consequently, as the level of total *V. parahaemolyticus* increases so does the number of pathogenic *V. parahaemolyticus*. The second most influential factor for the Gulf Coast is the time between harvest and refrigeration (time unrefrigerated), the third is the weight or amount of oysters consumed, and the fourth is the temperature of the water at harvest time. Note that length of refrigeration time has the sixth largest effect in terms of size, but that the bar for this factor points in the negative direction because *V. parahaemolyticus* levels decrease as refrigeration time increases. As in the Gulf Coast, the most important factor for the Pacific Northwest was also *V. parahaemolyticus* levels in oysters at harvest. However, water temperature at harvest time was the second most important factor, followed by the weight of oysters consumed and the length of refrigeration time. Time unrefrigerated—the third most important factor for the Gulf Coast—was substantially less important for the Pacific Northwest. For the Mid-Atlantic, *V. parahaemolyticus* levels in oysters, water temperature, and grams of oysters consumed were the top three factors. Time unrefrigerated was the fourth most important factor for this region.

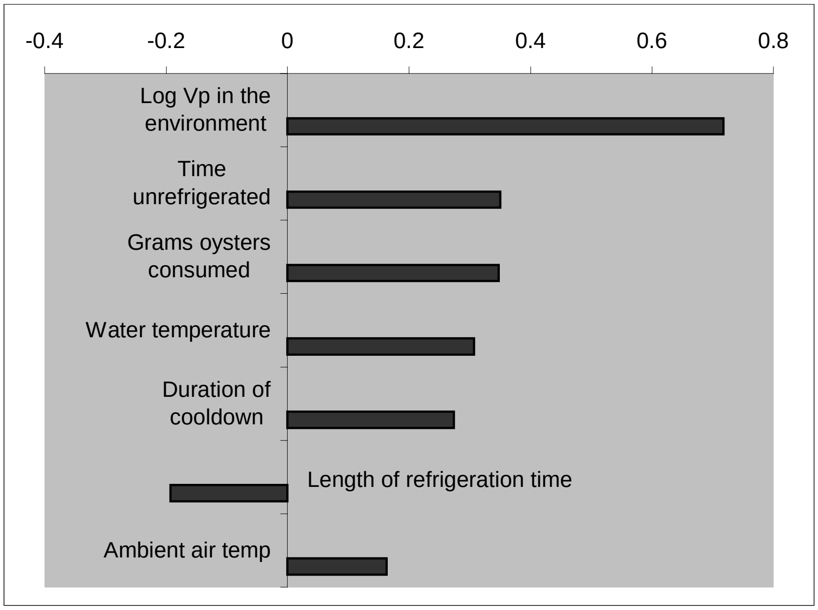

Figure 2. The tornado plot shows the relative importance of parameters that influence risk of *V. parahaemolyticus* (Vp) illness in the non-Louisiana Gulf Coast summer harvest.

Model results were validated by comparing predicted *V. parahaemolyticus* levels in oysters to real world data from a 1998-1999 collaborative Interstate Shellfish Sanitation Conference (ISSC)/FDA survey on *V. parahaemolyticus* levels in oysters at retail. These data were deliberately not used in the development of the model to provide an unbiased check of model outcome. In general, the mean *V. parahaemolyticus* levels predicted by the model compared well with the mean levels from the ISSC/FDA survey, particularly for the Gulf and Mid-Atlantic summers when the risk of illness is highest. For the Pacific Northwest, the model estimates are higher for the summer than the ISSC/FDA estimates and lower for the spring. The differences for the summer appear to be within the range of expected year-to-year variation, but the spring estimates are farther off, perhaps because the spring mean is based on a very small number of samples.

DISCUSSION

The objectives of this risk assessment were to determine the risk of illness resulting from ingestion of pathogenic *V. parahaemolyticus* in raw oysters, and to provide FDA with the information that it needs to evaluate the efficacy of *V. parahaemolyticus*-related public health programs. The risk assessment task force was also asked to evaluate the effectiveness of potential intervention measures for reducing or controlling *V. parahaemolyticus* levels, the current criteria for opening and closing harvest waters, and FDA's guidance of 10,000 total *V. parahaemolyticus* cells/g of food.

The risk assessment predicted the number of *V. parahaemolyticus* illnesses likely to occur in the future given a certain range of environmental and oyster handling conditions. These predictions are generally consistent with the CDC estimates for annual *V. parahaemolyticus* incidence.

The risk assessment also reviewed published studies on factors that may affect pathogenic *V. parahaemolyticus* levels in harvest waters and in shellfish, including water temperature, water salinity, contamination of shellfish-growing waters with ballast water, environmental contaminants, and immune status of oysters. Temperature was the only such factor incorporated into the quantitative model of *V. parahaemolyticus* illness. The model confirmed that water temperature at time of harvest was a major factor influencing initial *V. parahaemolyticus* levels in oysters and the number of *V. parahaemolyticus* illnesses. Air temperature was also found to greatly influence the growth of *V. parahaemolyticus* in oysters after harvest and thus, *V. parahaemolyticus* levels in oysters at the time of consumption.

The model also showed that the effect of different parameters varied by region and by season; e.g., water temperature was a more important determinant of illness levels in the Mid-Atlantic and Pacific Northwest than in the Gulf. However, for all regions, as one would expect, the more oysters one eats, the more likely it is that one will become ill.

The risk assessment model also demonstrated that the single most important factor related to the risk of illness caused by *V. parahaemolyticus* is the level of *V. parahaemolyticus* in oysters at the time of harvest. Accordingly, intervention measures aimed at controlling or reducing levels of *V. parahaemolyticus* in oysters should have a direct bearing on controlling or reducing the risk associated with this pathogen. Model simulations indicated that several proposed intervention measures would be effective in decreasing viable *V. parahaemolyticus* counts in oysters and the probability of *V. parahaemolyticus* illness. Cooling oysters immediately after harvest and quick freezing of oysters both reduced *V. parahaemolyticus* counts and illness estimates, while the effect of mild heat treatment on oyster levels practically eliminated the likelihood of illness. Modeling also showed that *V. parahaemolyticus* densities decreased slowly but steadily during refrigerated storage, and that frozen storage also decreased viable *V. parahaemolyticus* oyster densities. Both measures thus decreased the probability of illness due to *V. parahaemolyticus.* As noted above, the risk assessment was asked to evaluate the FDA guidance level of 10,000 cells/g. The model made it possible to develop a mathematical means of relating potential microbiological criteria with both the predicted percentage of illness prevented and the predicted percentage of the oyster landings that would no longer be available to consumers if the criterion could be implemented with 100% efficiency (Figure 3). This analysis suggests that in the absence of subsequent post harvest mitigations, "at harvest" guidance levels of 100,000, 1,000 and 100 total *V. parahaemolyticus* per g could (potentially) reduce the illness rate by 2%, 50% and 90% with corresponding losses of 0.3%, 25% and 70% of the harvest, respectively.

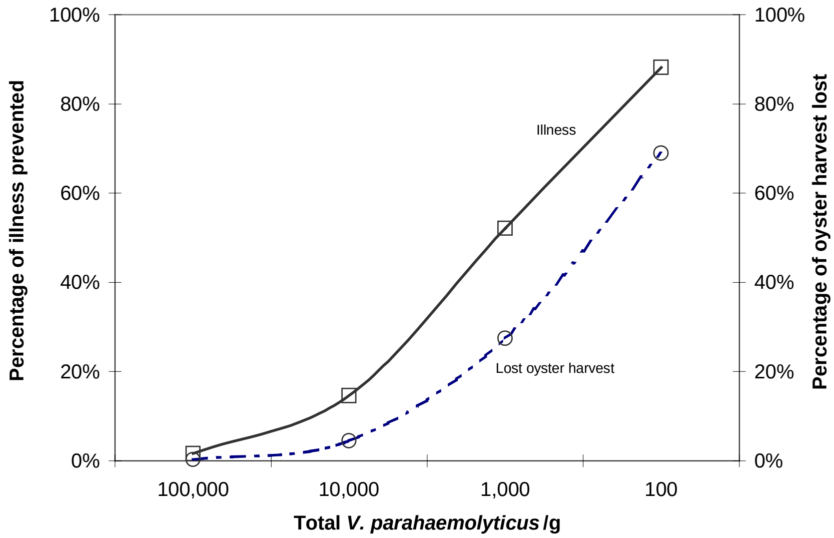

Figure 3. Potential effect of control of total *V. parahaemolyticus* per g at harvest (Louisiana Gulf Coast summer harvest).

The risk assessment also reviewed the effect of preexisting conditions on the risk of developing *V. parahaemolyticus* gastroenteritis or *V. parahaemolyticus*-related septicemia. Epidemiological studies indicate that people with certain preexisting conditions, such as renal or liver disease, peptic ulcer, diabetes, or immunodeficiency, and people who use antacids or have had gastric surgery are more likely to advance from gastroenteritis to septicemia once infected with *V. parahaemolyticus* than are healthy people. However, other epidemiological studies suggest that patients with preexisting conditions are not more susceptible than healthy people to contracting *V. parahaemolyticus* gastroenteritis.

The recently adopted ISSC interim control plan for monitoring levels of pathogenic *V. parahaemolyticus* at harvest is intended to prevent the harvesting of oysters (for raw consumption) from growing areas where relatively high densities of pathogenic *V. parahaemolyticus* are present. The potential effectiveness of this control plan could not be evaluated quantitatively, because not enough data are available for a quantitative model. However, the sensitivity analysis indicated that *V. parahaemolyticus* levels in oysters at harvest is the most important factor in determining the risk of illness in the absence of subsequent post harvest mitigations such as mild heating or frozen storage.

The risk assessment identified important data gaps. These gaps, which need to be addressed by research or further data collection, include the following topics: the prevalence of pathogenic *V. parahaemolyticus* in shellfish and in shellfish harvest waters; factors other than temperature that influence the presence of pathogenic strains; the role of oyster physiology and immune status in levels of *V. parahaemolyticus*; growth rate and survival of *V. parahaemolyticus* in oysters; rates of water turnover in shellfish harvest areas (based on levels of freshwater flow, tidal changes, winds, and depth of harvesting area); the infectious dose for pathogenic strains, i.e. how many *V. parahaemolyticus* organisms are required to cause illness; the effects of stomach acid production, food matrix, or immune status on dose-response relationships; and consumer handling practices of oysters prior to consumption. In addition, improved global public health surveillance of *V. parahaemolyticus* would identify new epidemic strains as they emerge.

In summary, this draft risk assessment significantly advances our ability to describe the current state of knowledge about *V. parahaemolyticus*, an important foodborne pathogen. It simultaneously provides a framework for integrating new scientific knowledge and evaluating its impact on public health. The results of the assessment are influenced by the assumptions and data sets that were used for Exposure Assessment and Hazard Characterization. The FDA is actively seeking new information, scientific opinions, or data during the public comment period. FDA anticipates that periodic updates to the risk model will continue to reduce the degree of uncertainty associated with risk estimates, and that these updates will assist FDA in making the best possible decisions and policies for reducing the risk posed by *V. parahaemolyticus* in raw molluscan shellfish.