June 15, 1999

To: Dockets Management Branch (HFA-305)
Food and Drug Administration 5384 '99
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

From: Pacific Coast Shellfish Growers Association

Subject: Parameter Identification for a Risk Assessment for *Vibrio parahaemolyticus* in Raw Molluscan Shellfish
Docket No. 99N-1075

The comments that will be provided here are an addendum to another memo sent under cover of the Molluscan Shellfish Institute and signed by a consortium of commercial shellfish growers. Please refer to that memo, which summarizes several of our concerns here on the West Coast. This memo is being sent to clarify several issues or data that were inaccurate in regards specifically to the West Coast.

On page 9 of the "Parameter Identification" report issued at the May 26 meeting in Chicago, the confirmed cases of Vibriosis has combined both commercially and recreationally harvested oysters. It is an important distinction in terms of developing more effective control methods, for obviously commercial operators have no means of controlling individuals that chose to harvest oysters on their own.

The difference between commercially and recreationally harvested shellfish is also an important distinction because the West Coast industry has responded very proactively to the risk associated with *Vibrio parahaemolyticus.* For the past two summers, during the warmest weeks, shellfish growers have voluntarily shut down harvest and sale of shellfish intended for raw consumption. The first voluntary closure occurred in 1997, in response to an unusual number of illnesses on the West Coast. Illnesses virtually ceased after the shut-down. We implemented the same approach in 1998, literally within hours of learning of two illnesses associated with the consumption of raw oysters. That was August 4, 1998. If you scan the Washington state data already provided to the Task Force, you will see that illnesses from commercial product once again ceased after implementing these voluntary industry closures..

The Task Force should be aware of research work being done here on the West Coast that is apparently not currently being considered in the body of studies, at least as listed in the Risk Assessment Parameters document bibliography. Dr. Haejung An, with the Oregon State University, has conducted extensive research on *Vibrio parahaemolyticus* and should be tapped as an important resource. Dr. Haejung has noted that the cases of gastroenteritis that have been confirmed from the U.S. Coastal waters are Urease positive/Kanagawa negative. Septicemia cases in the U.S. have been linked, however, with Kanagawa positive strains. She will be working with two graduate students over the summer to conduct research exclusively on Vibrio parahaemolyticus.

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Dr. Haejung, who is sending her comments under separate cover, has recommended the following research be included in the Risk Assessment:

Kelly, Michael T.; E.M.N. Stroh. 1988 Journal of Clinical Microbiology. "Temporal Relationship of *Vibrio parahaemolyticus* in Patients and the Environment" Vol. 26, Pgs 1754-1756.

Kelly, Michael T., E.M.N. Stroh, 1989 Journal of Clinical Microbiology. "Urease Positive, Kanagawa Negative *Vibrio parahaemolyticus* from Patients and the Environment in the Pacific Northwest." Vol. 27, Pgs 2820-2822.

Nolan, Charles N.; Ballard, Jane; Kaysner, Charles; Lilja, Jack; Williams, Leslie P; Tenover, Fred C. 1984 Diagnostic Microbiol. Infect. Diseases. "Vibrio parahaemolyticus, Gastroenteritis: On Outbreaks Associated with Raw Oysters in the Pacific Northwest. Vol 2, pgs 119-128.

On page 10 of the report, please note there is an error regarding the harvest area cited as contributing to 67% of the *V. parahaemolyticus* illnesses in 1998. It should read "HOOD CANAL" not Quilcene Bay, which is only one bay along a long finger of water that makes up Hood Canal. As the Task Force examines environmental parameters, it should be noted that this canal is a portion of Puget Sound in Washington State, prone to warmer waters and less tidal flushing than found in most other oyster growing areas along the Pacific Coast.

As was mentioned in the joint industry memo, we believe it is critical for the Task Force to strongly consider the ramifications of the effects of the last two warmer than average summers and observe if this trend continues before developing any far-reaching policies.

Another critical difference between the coasts that does not appear to currently be within the scope of the Risk Assessment is the variations that may occur in incidence, virulence and strains in the numerous oyster species cultivated here on the West Coast. Commercial oyster species include Pacifics, Kumamotos, European Flats, Atlantics and Olympias. Tasmanian oysters may eventually become commercially available here as well.

On page 15, the harvesting process depicted here is typical of methods commonly used in the Gulf and Atlantic Coasts. The majority of shellfish production on the West Coast, however, is harvested off beaches exposed during low tides. Oysters are typically harvested directly from the beach into steel mesh containers which are later retrieved by vessel at high tide and transported a short distance to processing plants with on-site refrigeration or a truck which delivers the live shellfish, usually within a four hour period, to a refrigeration unit. Culling may occur directly on the beach during the harvest or in the processing plants. A small percentage of the production directed at live half-shell consumption is culled and bagged for sale directly on the beach. These are typically transported short distances to shore-side refrigeration or trucks which deliver the live

shellfish, usually within a four hour period to a refrigeration unit. Some shellfish growers use drag dredges to harvest onto barges. The location of West Coast beds are typically minutes from dock or shore-side unlike the off-shore harvests typical in the Gulf of Mexico, where shellfish may sit out on harvest vessels for hours while the boat returns to port.

Also on page 15, it is stated that most raw oysters are consumed at restaurants. For the purposes of this Risk Assessment, this distinction may be unimportant, however, here on the West Coast consumers are just as likely to purchase their oysters directly from a retailer and eat them at home, raw or barbecued, as at a restaurant.

On page 18, under the section titled "Refrigeration storage effects *on V. parahaemolyticus*," it is noted that there is no apparent decrease of V.p densities in Washington oysters after three days on ice. We only have anecdotal evidence related to this, but it may be worth noting: This past summer, one of our members in California was purchasing oysters from a South Puget Sound growing area prone to high V.p counts. He insisted the product be shipped in large quantities of ice to assure the shellfish were kept cold during transport. Every lot he received was diligently tested by an approved lab for V.p. Although the counts coming out of Washington were low -- well below action levels – by the time it had reached California, well chilled in ice, the V.p had dropped to non-detectable levels! Certainly this points to a potential for control of V.p that should be explored!

Repeatedly in this document, and throughout the presentations made in Chicago, references were made to *V. vulnificus*. As an example, under the section "Effect of processing on *V. parahaemolyticus* levels, on page 19 it states: "*V. vulnificus* levels were not affected by commercial shucking and blowing procedures." Again, on page 20: "Depuration was not effective for reducing *V. vulnificus* in oysters because it multiplied within the oyster's tissues." I think it's possible to develop hypothesis from this, but surely we can't draw any scientific conclusions regarding *V. parahaemolyticus*.

On page 26, the data for oyster landings in 1997 is grossly inaccurate. Given the difficulty in obtaining consistent, accurate data on shellfish production, this is not surprising. According to the production figures published by the Western Regional Aquaculture Center, the states of Washington, California, Oregon and Alaska combined produced 68.1 million pounds of oysters in 1997, not 5.4 million as indicated in the Risk Assessment document. The 68.1 million pound figure provided here includes both shucked product and shellstock, with shucked product converted into shellstock numbers to provide a single consistent figure.

Our growers here on the Pacific Coast, and as noted in the joint memo sent from the commercial shellfish consortium, are extremely concerned with the apparent policy of the FDA to dissuade the public from eating raw oysters entirely. We have strong objections to the comments made by Michael DiNovi, and in print in the report, which are entirely inappropriate. It most certainly is the role of the FDA to protect the public from tainted product. It is certainly the FDA's role to develop the means for identifying and

controlling tainted product. It is most certainly *not* the role, nor should it be, of FDA to use their considerable power and sway to frighten the public into believing shellfish in general or oysters in particular are dangerous for their health. When was the strategy developed, and by whom was it sanctioned to "limit...exposure of the public to raw molluscan shellfish"? In point of fact, the chief goal and original intent of the ISSC was to assure raw shellfish are safe for consumers. Raw oysters are among the world's most perfect, nutritious, digestible proteins. When grown in pure waters and monitored to assure its purity, they should continue to be made available to an educated and free-acting consumer.

Having attended the May 26 Risk Assessment Task Force meeting, it was unclear to me whether the Task Force intends to pursue the assessment of risk for all shellfish or for live oysters alone. While most of the information seems to point rather clearly to raw oysters as the primary cause of V.p illnesses, some of the presenters suggested that the Risk Assessment may take more of a global approach and assess the risk associated with all shellfish. From a policy perspective, it would seem logical to consider all shellfish in the Risk Assessment so that concerns about other shellfish can either be laid to rest or incorporated into a control plan. Logically then, the final assessment would drive the Economic Impact assessment. I understand, however, that the economic impact assessment is well underway. This brings me, then, to my next question. How far-reaching is the economic assessment? Is it including only live oysters, or are other species and shucked product being evaluated as well? Hopefully, these two investigations will dove-tail, so that we can compare apples to apples, or in this case, oysters to oysters.

In closing, we urge the Task Force overseeing this Risk Assessment to put illnesses caused by shellfish consumption in perspective. Compare it to other foods. The CDC recently published a list of foods most often implicated in food-borne illnesses and the pathogens that cause those illnesses. Shellfish are at the very bottom of this list. *Vibrio parahaemolyticus* doesn't even register. Strawberries and asparagus are more often implicated in illnesses. Other animal proteins are particular culprits in food-borne illnesses. We applaud any scientific attempts to make our shellfish even safer to consume, but applying stricter regulations to this industry when it causes a statistically insignificant number of illnesses compared to other food industries strikes us as quite ill advised.

Thank you for the opportunity to comment. As we noted at the meeting in Chicago, we hope this effort yields the industry more precise scientific tools for assuring our customers' health and safety. I look forward to speaking with any members of the Task Force who may wish to clarify the data provided here.

Sincerely,

Robin Downey

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