STATE OF CONNECTICUT

DEPARTMENT OF AGRICULTURE

Bureau of Aquaculture and Laboratory

April 16, 1999

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TO: Dockets Management Branch(HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

FROM: Malcolm Shute, Supervising Environmental Sanitarian, representing
Connecticut Department of Agriculture, Bureau of Aquaculture,
P. O. Box 97, Milford, CT 06460

RE: Federal Register Notice
Performance Standards for *Vibrio vulnificus*, Request for comments
Docket No. 98P - 0504

The Department of Agriculture has reviewed the U.S. Food and Drug Administration's(FDA) *Federal Register* notice requesting comment on the Center for Science in the Public Interest(CSPI) petition and on several specific questions relating to the petition.

The Connecticut Department of Agriculture recommends that FDA delay action on this petition until actions on this matter have been concluded this year by the Interstate Shellfish Sanitation Conference(ISSC) which is currently addressing this issue with FDA. If FDA cannot delay action on this petition, then it is the Department's recommendation that the petition be denied at this time.

CSPI's request for zero tolerance for V. vulnificus, together with possible future proposals by CSPI or other groups requesting zero tolerance for other pathogens will lead to elimination of shellfish consumption in the raw(or live) state as has been practiced world wide for over a hundred years. In order to demonstrate zero tolerance, each shellfish must be tested, which leads to destruction of the raw live product as we know it. In this case, zero tolerance will require cooking or processing the product prior to consumption if destruction of the product by testing is to be avoided. There are few if any foods in which FDA requires a zero tolerance for pathogens or chemicals. Federal requirements on milk and drinking water are very restrictive, but are applied to these products in order to safe guard the health of all individuals in general, that might be affected by pathogens or certain chemicals. These requirements have not been strengthened to protect or respond to the health needs of certain select individuals whose health may still be at risk due to their particular predisposition for health risk regarding these or other food products as would be required for zero tolerance.

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FDA is soliciting comments on eight questions in addition to the CSPI petition. These question must be addressed. Currently FDA and the ISSC are attempting to address these issues. FDA may have the prime responsibility to conduct these assessments. At this point FDA should have resolved its questions concerning AmeriPure technologies since it has reviewed AmeriPure data and has allowed AmeriPure to market no-longer-alive product as a live shellfish product containing no *V.vulnificus*. If zero tolerance is accepted, consideration must be given to the perception that FDA and CSPI are in support of AmeriPure since AmeriPure currently is the only apparent company able to produce *V.vulnificus* free oysters and holds the patents for these technologies.

Question "8" suggests establishing a zero tolerance for *Vibrio parahaemolyticus* due to a large number of illnesses from a particular pathogenic strain of this organism. Establishing a zero tolerance for *Vibrio parahaemolyticus* would probably eliminate the sale of live shellfish for direct consumption because of the testing requirement and the likelihood of finding *V.parahaemolyticus* in both warm and cold waters of the United States. Current technologies are not at a level to easily differentiate pathogenic strains from the normally occurring forms in the different geographic areas of the United States. Data is not currently available to indicate when an area may be reopened.

States, other than the southern states that have been linked to illnesses, such as New York are concerned that zero tolerance will lead to required testing of all shellfish if an illness appears to be linked to the product and the elimination of shellfish as a live resource for consumption.

A mechanism to control *V.vulnificus* infections may already be in place but not enforced by FDA. This mechanism would not require zero tolerance, and was promulgated by FDA. On December 18, 1997, FDA's Seafood Hazard Analysis Critical Control Point(HACCP) Regulation went into effect. If illnesses are "likely to occur" from seafood products, such as *V.vulnificus* infection from oysters, it is the responsibility of seafood dealers to address this in their Hazard Analyses and incorporate a control point to prevent those illnesses in their HACCP Plans. A critical control point could be not selling a product that in a particular season is likely to cause illness, labeling the product with a "requires cooking" warning, or switching to a processed product free of *V.vulnificus* for that time period.

Control of the hazards that are related to the consumption of raw chicken or raw pork occurs at the wholesale/retail level. FDA has not required a zero tolerance for salmonella in chicken or zero tolerance for trichina in pork. In a similar fashion, with advise from state control authorities and FDA, seafood wholesalers/retailers with their HACCP Plans should control *V.vulnificus* infections. If the seafood dealers conduct Hazard Analyses of their product and determine that illness from *V.vulnificus* is "not likely to occur", then they have addressed the issued and no additional control including "zero tolerance" is required. If, however, they find that their product is "likely to cause illness", then they must address the issue and FDA should take the responsibility to enforce its regulation which it designed to eliminate these illnesses.

FDA should delay action on, or deny the CSPI petition and enforce its Seafood HACCP Regulation.

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