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The following comments on CSPI's petition requesting that FDA establish a standard of "nondetectable" for the marine bacterium *Vibrio vulnificus* in raw molluscan shellfish are submitted by the New York State shellfish sanitation program.

CSPI's desire to protect the health of shellfish consumers is commendable. However, that group's petition to FDA seeking the specified performance standard for raw molluscan shellfish, which is *not* a dietary staple, is an attempt to provide absolute assurance that a raw protein food product is 100% risk free. That goal is beyond the capacity of any food quality assurance program.

The incidence of fatalities caused by *Vibrio vulnificus* in shellfish, almost exclusively oysters harvested in states along the Gulf of Mexico, is a primarily a medical problem associated with identifiable at-risk consumers. It is not a public health problem. It is a problem that should be addressed with a solution that does not unnecessarily increase the cost of production for the oyster industry nationwide and simultaneously deny millions of shellfish consumers, who are not at risk, the right to continue eating raw molluscan shellfish in the traditional, unprocessed form that they demand and clearly prefer.

The best way to reduce the incidence of morbidity and mortality in at-risk consumers is through education of health care providers who treat those at risk consumers. They should pass on a simple, straightforward advisory to their patients who are at-risk for experiencing serious health problems by exposing themselves to food borne pathogens: Do not eat raw animal protein products of any kind. Efforts should also be made to directly educate at-risk consumers through patient support groups and other organizations whose memberships are comprised of a high percentage of at-risk individuals.

FDA and ISSC have engaged in efforts to educate health care providers and at-risk consumers for only a few years. It is too soon to consider those efforts unsuccessful because the annual occurrence of 15 to 20 deaths among at-risk consumers has not been reduced to zero. Those educational efforts must be maintained and should be stepped up. Educational efforts to change behavior with regard to lifestyle choices such as diet can only be effective if they are properly directed, consistent and long term.

The AmeriPure Co. technology is not readily employable by the shellfish industry in New York State. The barrier is simple: Lack of consumer demand for dead oysters on the half shell. Approximately two years ago, oysters treated with that technology began appearing in wholesale markets and retail establishments in the New York City metropolitan area. That was a short lived. Wholesalers and retailers were not satisfied with the shelf life if the product. New York area consumers prefer and demand a live product, with all the texture, flavor and natural "liquor" characteristic of a live oyster.

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A post-harvest treatment performance standard for *Vibrio vulnificus* is not suitable for oysters from all parts of the United States. If a performance standard is developed, it must be based on sound scientific information that has identified a minimum infective dose for at-risk populations. A performance standard for post harvest treatment should only be applied to oysters from states which have been definitively identified as the source of shellfish that have caused *V. vulnificus* related deaths. In addition, a review of the records on *V. vulnificus* related morbidity and mortality must be conducted to determine whether post-harvest treatment of oysters from those states should be required throughout the year or only during months when *V. vulnificus* illnesses are most prevalent.

Under no circumstances should a performance standard for post-harvest treatment of other bivalve molluscan species be mandated if those species *have not* been linked to *Vibrio vulnificus* deaths. Nor should a performance standard be mandated for other bivalve mollusks based on the sporadic occurrence of *Vibrio vulnificus* illnesses or deaths in at-risk individuals.

The only quantifiable benefit of a performance standard for mandated post-harvest treatment would be the economic benefit enjoyed by the purveyor of the post-harvest technology. There is no quantifiable benefit to the at-risk population. Post harvest treatment, as it exists today, allows at-risk consumers to eat oysters in a form that *somewhat* resembles a live oyster on the half shell. In fact, that oyster is dead and is no safer, from a risk assessment perspective, than an oyster that has been fully cooked. The efficacy of the currently available technology has not been determined with regard to other potentially pathogenic bacteria and viruses. Eating thoroughly cooking oysters, an option that is readily available to all at-risk consumers at the present time, remains the safest option for at-risk consumers because it destroys a wide range of pathogens that might be in shellfish and raw animal protein foods in general.

Requiring post-harvest treatment comes at some considerable and as yet undetermined cost. There would a quantifiable cost to the shellfish industry. There would also be a non-quantifiable cost to the vast majority of shellfish consumers who are not at-risk of illness from *Vibrio vulnificus*. That cost would be in the form of depriving those consumers of the opportunity to consume oysters in the traditional, raw form they have demanded and enjoyed for decades.

Finally, the question of requiring a performance standard for other *Vibrio* species was posed in the request for information and views. New York's shellfish sanitation program strongly opposes such a performance standard. The Interstate Shellfish Sanitation Conference (ISSC) is the appropriate forum for dealing with problems associated with *Vibrio parahaemolyticus* illnesses linked to the consumption of shellfish.

At its 1998 meeting, the ISSC adopted an Interim Control Plan (ICP) for *Vibrio parahaemolyticus* to be used by states which have been the source of shellfish which have caused *V. parahaemolyticus* illnesses in consumers. Although it has been recognized that the ICP has some shortcomings they will be addressed during the 1999 meeting of the ISSC. In addition, the action of the ISSC in 1998 requires that the ICP be reviewed in detail at its meeting in 2001. Before any post-harvest treatment is mandated in a hasty attempt to deal with problems caused by *V. parahaemolyticus*, the states' shellfish sanitation programs should be afforded the opportunity to implement and assess the effectiveness of the ICP.

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