CENTER FOR
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Dr. Margaret A. Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

This coming April a deadly foodborne disease outbreak will start and continue unabated through November. This "outbreak" will cause about 30 serious illnesses and, tragically, 15 deaths, just as it does every year. That is more deaths each year than occurred in the infamous Jack-in-the-Box and Peanut Corporation of America outbreaks *combined* – two watershed events that led to major reforms in food safety regulation. Yet, the Food and Drug Administration ("FDA") and other health agencies have made little progress in preventing the annual "outbreak" linked to *Vibrio vulnificus* in raw oysters from the Gulf of Mexico – even though solutions to the problem are well-known.

The Center for Science in the Public Interest ("CSPI") believes that the *Vibrio* problem must be solved and that FDA has never had better tools to take action. Attached is our new petition that calls for a *V. vulnificus* performance standard of "non-detectable" in raw and processed raw shellfish. The petition relies on section 104 of the FDA Food Safety Modernization Act ("FSMA"), which *requires* the FDA to issue performance standards for significant contaminants. Because of *Vibrio's* annual causation of deaths and illnesses, the public health community has long considered *V. vulnificus* as a significant hazard in shellfish. Meanwhile, the shellfish industry could use any of several commercially viable methods for meeting a standard, including the four validated processing methods or by sending oysters harvested from contaminated waters to be shuck for cooking rather than offering them for raw consumption. The petition anticipates industry will choose the most cost-effective, validated means of meeting the performance standard. In this way, the petition is consistent with the Hazard Analysis Critical Control Points program for fishery products, as well as the preventive control system described in FSMA.

This is not the first time CSPI has petitioned FDA for controls on *V. vulnificus*. In 1998, we requested a performance standard supported by mandatory post-harvest processing. FDA denied our petition in 2002 and, instead, relied on the Interstate Shellfish Sanitation Conference ("ISSC") to take action. Obviously, that organization did not implement effective controls, largely because it is dominated by the shellfish industry and governments of states that have shellfish industries. Consumers have waited long enough. In the nine years since FDA denied our original petition, 262 people have suffered serious illnesses including 121 people who died – all of which could have been averted. In this same period, California virtually eliminated

illnesses from *V. vulnificus* by adopting the approach recommended by CSPI in its 1998 petition. California's experience confirmed that CSPI's proposal, had FDA approved it, could have saved many lives.

The ISSC plans have consistently failed to protect consumers. We respectfully request the agency not to repeat past mistakes and, instead, protect consumers from a deadly, but preventable, foodborne disease by taking quick, positive action on the attached petition.

Respectfully submitted,

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Enclosure