

February 23, 2015

Laura Wigand Johnson
Washington State Department of Health
PO Box 47824
Olympia, WA 98504-7824

RE: Revisions to WAC 246-282-006, Washington State *Vibrio parahaemolyticus* (Vp) control plan: Proposed Rule Making, Jan. 26, 2015.

Thank you for this opportunity to comment on the proposed revisions to the Washington State *Vibrio parahaemolyticus* control plan. The Center for Science in the Public Interest (CSPI) supports efforts to better protect consumers from the health risks associated with contaminated raw oysters and, therefore, welcomes the opportunity to provide views on the Health Department's proposed rule. CSPI is a nonprofit health advocacy and education organization focused on nutrition, health and food safety issues. We are supported principally by the 850,000 subscribers (24,267 in Washington State) to *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Stronger public health policies are needed to control the risk that *Vibrio* poses to consumers of raw shellfish. The Centers for Disease Control and Prevention has documented the extraordinary trend of ever increasing numbers of illnesses attributed to *Vibrio*,¹ indicating this is an area where control efforts to date have proven ineffective.² *V. parahaemolyticus* accounts for a majority of the cases reported and is estimated to cause 35,000 illnesses annually.³ Consumers exposed to *V. parahaemolyticus* most often suffer self-limiting gastroenteritis, but illnesses can progress to septicemia and require hospitalization or end in death.⁴ When monetized, the illnesses are estimated to cost consumers in excess of \$40 million annually in premature death, medical costs and

¹ CDC, *Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2013*, 63 MMWR 328, April 18, 2014.

² Anna Newton, et al., *Increasing Rates of Vibriosis in the United States, 1996-2010: Review of Surveillance Data From 2 Systems*, 54 *Clinical Infectious Diseases* S391 (2012).

³ Elaine Scallan, et al., *Foodborne Illness Acquired in the United States—Major Pathogens*, 17 *Emerging Infectious Diseases* 7-15 (2011).

⁴ FDA Center for Food Safety and Applied Nutrition, *Quantitative Risk Assessment on the Public Health Impact of Pathogenic *Vibrio parahaemolyticus* in Raw Oysters*, July 2005 (hereinafter "Vp Risk Assessment"); Tanya Roberts, Barbara Kowalczyk & Patricia Buck, *The Long-Term Health Outcomes of Selected Foodborne Pathogens*, Center for Foodborne Illness Research & Prevention (2009) available at http://www.foodborneillness.org/cfi-library/CFI_LTHO_PSP_report_Nov2009_050812.pdf (last accessed Feb. 11, 2015).

economic losses.⁵ These are health impacts and costs that are easily preventable through use of post-harvest processing technologies, and that can be reduced through better harvesting and handling practices.⁶

CSPI supports the goal expressed by the Health Department for its new approach of preventing illnesses by basing control measures on environmental conditions rather than the occurrence of illnesses. This is the right focus for a modern preventive food safety program. Additionally, many of the proposed changes to the state's *V. parahaemolyticus* control plan are positive steps toward achieving that goal, such as categorizing harvest waters for risk and reducing the time from harvest to cooling.

The proposed rule could be strengthened, however, to better protect public health by adding provisions that address those instances where the control plan may fail and improve accountability. We recommend the following changes:

Restore authority to close waters. CSPI is concerned that the proposed rule removes authority to close waters in cases where multiple illnesses are linked to a particular harvest area in a short period of time. As drafted the revised rule places complete reliance on individual harvesters to stop harvesting if harvest temperatures are above a prescribed limit. This approach does not address an instance where illnesses are occurring in spite of the harvesting restrictions. To address this, the Health Department should retain authority to order waters closed as an emergency measure. This could be accomplished by inserting the following provision after subsection 10.

(11) The department may order a growing area closed for 24 hours if after an investigation it determines that no less than four sporadic cases of *Vibrio parahaemolyticus* illnesses are epidemiologically associated with oysters from the growing area harvested in compliance with the requirements of subsection (10), and harvested within 30 days of each other. At the end of the 24 hours the department must:

(a) Immediately categorize the growing area as Category 2 or Category 3, as appropriate,

(b) Evaluate the growing area by measuring the harvest temperature and conducting an assay of the level of *Vibrio parahaemolyticus* in oysters sampled from the area, and

(i) Order the growing area closed for an additional 24 hours, or

⁵ USDA Economic Research Service, *Cost of Foodborne Illness Estimates for Vibrio parahaemolyticus*, available at [http://www.ers.usda.gov/datafiles/Cost Estimates of Foodborne Illnesses/Pathogen/Vibrio para.xlsx](http://www.ers.usda.gov/datafiles/Cost%20Estimates%20of%20Foodborne%20Illnesses/Pathogen/Vibrio%20para.xlsx) (last accessed Feb. 11, 2015).

⁶ Vp Risk Assessment, *supra*.

- (ii) Open the growing area, or
- (c) Open the growing area.

Retain authority to hold harvesters accountable. CSPI is concerned that the proposed rule does not provide adequate accountability when a harvester violates the requirements of the provision. Under the existing control plan, a harvester or dealer whose practices cause multiple illnesses is subject to retraining, potential loss of license and other disciplinary action. The proposed rule has no accountability provision other than penalties under WAC 246-282-120. The Health Department should retain authority within the control plan to take action against harvesters or dealers whose practices result in illnesses from *V. parahaemolyticus*. This could be accomplished by inserting the following provision after the amended subsection (11) above.

(12) If the investigation under subsection (11) determines the illnesses are attributable to the same harvester or dealer, the department shall conduct an investigation in accordance with the requirements as stated in the NSSP Model Ordinance to determine if the illnesses are the result of harvester or dealer practices or are linked to the growing area as the probable source. If the harvester or dealer practices are reasonably likely to have caused the illnesses:

(a) The harvester or dealer shall retake the training identified in subsection (___)(a) of this section prior to renewal of their next year's license,

(b) The department may take disciplinary action against the harvester or dealer, and

(c) The department will evaluate whether to associate the illnesses with the growing area.

Restore provision for intertidal harvest times. CSPI is concerned that the proposed rule does not adequately define the time of harvest. This is especially troubling in regard to harvesting from intertidal areas where oysters may be exposed during low tide. To address this, the Health Department should include a definition of "time of harvest" under subsection (3).

(e) "Time of harvest" means the time after the first oyster is exposed to the air as follows:

(i) The intertidal (exposed) time of harvest begins after the first oysters to be harvested are exposed to the air by the receding tide.

(ii) The submerged time of harvest begins after the first oysters harvested are exposed to the air and have been placed onto a conveyance, such as a barge or boat. Submerged harvest includes

dredge harvesting or retrieval of harvest tubs, bags, baskets, or other containers of oysters previously filled which have been under water for a minimum of one hour for coastal areas and four hours for Puget Sound growing areas.

The additions proposed above would improve the potential for the proposed regulation to achieve its public health goals without increasing costs to the oyster industry. Costs are not increased because the provisions in the first two proposed changes do not take effect unless the proposed control plan breaks down and illnesses occur. (Hopefully, the preventive aspects of the proposal will prove effective, but if controls fail, the Health Department should not depend solely on categorization and increasingly stringent time and temperature controls as the only means of protecting public health.) Meanwhile, adding a definition of “time to harvest” provides the industry with greater clarity as to its responsibilities. Since the recommended definition is taken from the current control plan, it should not impose any additional inconvenience or costs on the oyster industry.

CSPI believes the Health Department should consider three additional issues as it determines how to implement the control plan.

First, does the Department intend to categorize areas on a rolling five year basis?⁷ In such a case, the effectiveness of the control plan may result in high-risk growing areas yo-yoing in and out of category 3 status. For example: An area is designated as category 3 based on having been the source for five or more illnesses in the previous five years. The category 3 requirements prove effective for a five year period, and the area is restored to category 1 status. In that status, the harvest time and temperature controls are again ineffective for controlling *V. parahaemolyticus* contamination and as a result, the area is again the source of illnesses. To avoid this, the Health Department should consider some objective measurement of conditions in the water before raising the status of a category 2 or 3 growing area. This could be done by taking into account illnesses from non-commercial harvesting within the same area and sampling the water for *V. parahaemolyticus* concentrations. If illnesses from non-commercial harvests occur and *V. parahaemolyticus* levels, on average, are not significantly different from the time when the area was first categorized, then the Health Department should evaluate these factors before opening the area to Category 1 harvesting.

Second, should the Health Department adjust categories in response to multiple illnesses? This is suggested in part by the amendments recommended above, which call for immediately re-categorizing growing areas in response to multiple illnesses. The Health Department should consider making it clear that category 1 and category 2 growing areas

⁷ This question arises because it is unclear whether the annual categorization under subsection 10 creates a permanent or rolling category designation. The Health Department should clarify this point before it implements the rule.

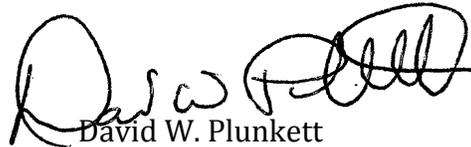
are subject to change during the harvesting season if multiple illnesses are associated with them.

Third, should the Health Department in moving to a preventive system based on environmental conditions exercise authority to close waters when it finds conditions warrant closure? The system described in the proposed control plan relies on harvesters and dealers to make the decision based on temperature measurements they take. To verify the system is working, the Health Department should consider conducting periodic testing. Based on the testing, it could alert harvesters to potential issues with air and water temperatures, direct harvesters to cease harvesting, and verify that harvesters are correctly measuring and recording temperatures during harvesting.

CSPI appreciates the efforts of the Washington State Department of Health to reduce the incidence of *V. parahaemolyticus* illnesses. The revised control plan is a promising start, but more could be done. The risk could be eliminated by requiring post-harvest processing to destroy *Vibrios* in any month when conditions indicate an increased risk. In the absence of such a requirement, stringent time and temperature limits on harvest and handling at least reduce the risk. We encourage the Health Department to further improve the effectiveness of the proposed *V. parahaemolyticus* control plan by adopting the recommendations in this comment.

If you have any questions on our recommendations, they may be addressed to David W. Plunkett at dplunkett@cspinet.org or by calling (202) 777-8319.

Sincerely,

A handwritten signature in black ink, appearing to read "David W. Plunkett", written in a cursive style.

David W. Plunkett
Senior Staff Attorney
Food Safety Program

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