William R. Jones, Ph.D.
Director, Division of Seafood Safety
Office of Food Safety, HFS-325
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Dr. Jones,

The Center for Science in the Public Interest (CSPI)\(^1\) disagrees with the recent Food and Drug Administration (FDA) decision to concur with a proposal that changes how states measure the effectiveness of their *Vibrio vulnificus* (*Vv*) management plans for raw oysters. *Vv* is a significant foodborne hazard that kills a higher percentage of its victims than any other foodborne pathogen. For those who survive, an infection can leave them physically scarred or disabled. On average, 30 cases occur each year with the majority of them traceable to oysters harvested from the Gulf of Mexico in the months of April to November. Because FDA’s decision allows the oyster industry to knowingly market contaminated food, it will result in consumers continuing to suffer debilitating and deadly foodborne infections from a preventable cause.

More than two decades have passed during which the industry could have remedied this problem. Effective measures for controlling *Vv* such as post-harvest processing (PHP) are available and validated. California, for example, has demonstrated that PHP is almost 100 percent effective at eliminating the threat of *Vv* in raw oysters. This led FDA in 2009 to announce its reformulated policy that measures which reduce the hazard, but fall well short of eliminating it, are insufficient to meet the purpose of the safety regulations, given the severity of the hazard and the availability of PHP technologies.\(^2\) Yet, the industry has insisted again-and-again on experimenting with ineffective measures like time-temperature controls at harvest. Those experiments have failed to reduce illness rates. Meanwhile, the cost of delay resulted in over 160 serious illnesses and 140 deaths since 2002 that reasonable and available controls could have prevented.\(^3\)

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\(^1\) The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.


\(^3\) 2002 is the year in which FDA denied CSPI’s petition for mandatory PHP of raw oysters harvested from the Gulf of Mexico. In its denial, FDA stated that failure of the ISSC’s *Vv* Control Plan would result in mandatory PHP. Although the ISSC’s plan failed in 2008, FDA did not enforce the consequences it promised consumers in its denial letter. See, Letter from John M. Taylor, III, Senior Assoc. Comm. for Regulatory Affairs, FDA, to Michael F. Jacobson, Exec. Dir., CSPI (Oct. 21, 2002).
The proposal, number 11-201A, adopted by the Interstate Shellfish Sanitation Conference (ISSC) in 2011, is one more attempt at using time-temperature controls. It replaces a risk-per-serving goal linked to a 60 percent reduction in the rate of illnesses with one based on illnesses per 100,000 servings without reference to an illness reduction goal. FDA initially refused to concur with the changes because they deviate from current FDA policy, and weaken previous control efforts targeted at a 60 percent reduction in the rate of illnesses. While FDA has not enforced its policy on effective measures to eliminate *Vv*, it has maintained the ISSC cannot roll back the clock on the 60 percent reduction goal. Since the proposal is less likely to achieve that goal, FDA was correct in its non-concurrence.

It is our understanding that FDA now believes it has a commitment from the ISSC to reduce illness rates by 60 percent and that it will be able to hold the states accountable for meeting the targeted reductions. As a result, the agency concurred with 11-201A in a brief Oct. 15, 2012, letter to the ISSC executive board. This action allows states to establish time-temperature standards for harvesting oysters based on a computer prediction of illnesses that will result from raw oysters produced by the state. However, the letter does not explain the basis for FDA’s decision to reverse its earlier non-concurrence.

In its letter of non-concurrence on Feb. 26, 2012, FDA stated it remained committed to PHP as the most prudent means of reducing illnesses from *Vv*. FDA acknowledged plans for conducting further studies into how PHP controls could be implemented and told the ISSC to continue controls targeted at a 60 percent reduction in the interim. Specifically, FDA asked the ISSC to address three areas of concerns and issues:

1. (a) FDA cited “significant concern” with the failure of the states to establish effective controls by closing growing areas, implementing PHP or diverting harvests to shucking, and noted that under ISSC supported controls “compliance by the industry has proven difficult.” Furthermore, there is no evidence these controls can achieve the 60 percent reduction goal.
   (b) FDA expressed its intent to evaluate the effectiveness of risk-per-serving standards based on their showing a 60 percent reduction in *Vv* illnesses in nationally reported cases associated with Gulf oysters.
   (c) In meeting the goal, FDA noted states cannot assume a generic 10 percent reduction in harvest and that 15 percent of oysters will be diverted to PHP. FDA believes this will vary state-to-state and year-to-year making it necessary for each state to provide data supporting its assumptions.

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4 The ISSC adopted the current risk per-serving goal in 2009, effective Jan. 1, 2012, basing it on a risk calculator FDA developed after the first *Vv* Risk Management Plan failed in 2008. The original management plan targeted a 60 percent reduction measured against the number of illnesses per unit of population in four states. The baseline in both plans was illnesses from 1995-1999. See, ISSC Summary of Actions: 2009 Biennial Meeting at 317; and Letter from Donald W. Kraemer, Deputy Dir., Office of Food Safety, to J. Michael Hickey, Chairman, ISSC, Apr. 6, 2010.
(2) FDA expressed concern that given the fluctuations in illness numbers and oyster production, assessing the effectiveness of time-temperature controls will be difficult.

(3) FDA requested the ISSC to develop:
   (a) Evaluation criteria for determining proper and effective use of the $Vv$ risk calculator;
   (b) Evaluation criteria for determining state $Vv$ control plan compliance with NSSP requirements;
   (c) Evaluation criteria for determining the effectiveness of state regulatory efforts to ensure industry compliance with state $Vv$ control plan requirements;
   (d) A formula for calculating state compliance with risk-per-serving standards; and
   (e) Actions and sanctions should a state be found out of compliance.  

The Oct. 15 letter does not detail how the ISSC responded on any of these concerns and issues nor explain why FDA believed its responses were adequate. Indeed, FDA has not released any information on the basis for its decision. At a minimum, consumers have a right to know the answers to questions raised by the agency in a public setting. Ideally, the public should have been afforded the opportunity to evaluate the answers and comment before agency action was finalized. This is especially true when the agency action changes policies in a way that directly impacts public health.

Based on information that is publically available and FDA’s history on this issue, we are skeptical of the agency’s ability to hold states accountable for meeting their obligations. Since 1977, FDA’s efforts to enforce stronger public health measures have repeatedly failed. Also, given the historic ineffectiveness of ISSC programs, consumers have serious doubts that states will achieve even the modest goals 11-201A sets. The success of its approach is heavily dependent on 100 percent compliance by the industry, a reality not supported by the Government Accountability Office (GAO).

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6 Id.
7 In 1977, Congress – at the behest of the oyster industry and states – blocked an FDA effort to improve state compliance with sanitation requirements. GAO, Problems in Protecting Consumers From Illegally Harvested Shellfish (Clams, Mussels, and Oysters), 7, June 14, 1984. In 1994, the industry used political pressure to stop a FDA proposal setting limits on summer harvesting of oysters. CSPI, Death on the Half Shell, June 2001. In 2008, FDA did not implement PHP as it had committed to do in 2002. See, Letter from John M. Taylor, supra note 3. When FDA finally attempted to implement PHP in 2009, the ISSC and oyster industry again used their federal and state political allies to block the agency. See, Joan Murphy, Gulf State Lawmakers Push FDA to Abandon New Oyster Policy, Food and Chemical News, 9, Nov. 16, 2009.
8 GAO, FDA Needs to Reassess Its Approach to Reducing an Illness Caused by Eating Raw Oysters, Sept. 2011 (GAO determined the probability of a $Vv$ risk calculator prediction matching actual illnesses in Louisiana is below 50 percent in most months even with full compliance, and falls to less than 1 percent at 80 percent compliance. Compliance rates, meanwhile, are impossible to know. Neither FDA, ISSC, state officials, nor the industry have data on compliance rates. However, stakeholders told GAO anecdotally that non-compliance was a known problem. A FDA official also expressed no confidence in the states’ ability to enforce compliance with time-temperature controls).
established conditions that will undermine compliance. In setting different time-temperature controls for oysters sold within the state there is increased likelihood that fraudulent labeling will flourish. We know this practice is widespread and that FDA does not believe states will engage in meaningful enforcement actions to prevent it. Meanwhile, the provisions in 11-201A on evaluating the effectiveness of a state’s plan are vague and rely on compliance information that neither the states nor FDA gather. Clearly there are palpable reasons for our skepticism.

The foregoing facts raise questions about FDA’s reasoning in concurring in a plan that appears predestined to failure. Therefore, we are requesting answers to the following questions:

- How are each of the issues and concerns expressed by FDA in its non-concurrence resolved by the ISSC.
- Why does FDA consider the ISSC’s answers adequate?
- What has changed since FDA issued its letter of non-concurrence on Feb. 26, 2012?
- Why are the conditions for concurring in 11-201A not memorialized in writing and made available for public examination?
- How is FDA’s decision a step forward to achieving public health goals?
- How will FDA evaluate the effectiveness of state plans?
- How long will states have to establish the effectiveness of their Vv control plans?
- Under what circumstances will FDA start an action to bring a state into compliance?
- What consequences will follow the failure of a state plan?
- Does FDA intend to continue its 2009 policy which requires PHP or equally effective controls for eliminating Vv contamination in raw oysters?
- If the policy has changed, how has FDA revised that policy and where is that revision announced?
- If FDA is continuing its 2009 policy, how does the decision to concur in 11-201A conform to that policy?

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9 We refer here to LA Rev. Stat. § 56:437 which allows oysters to go unrefrigerated for up to 5 hours if they are harvested for sale within the state, regardless of time-temperature limits based on 11-201A.
10 GAO (Sept. 2011) supra at 21-23.
11 Id. at 19-21.
We are deeply disappointed by FDA’s decision to reverse its position of non-concurrence with 11-201A. The agency’s action allows predictable levels of human suffering to continue for years beyond the date when consumers were promised relief from the preventable foodborne diseases caused by oysters contaminated with Vv. Our disappointment is heightened by FDA’s troubling lack of transparency in explaining how issues it raised in its non-concurrence are resolved. We are hopeful your response can shed light on FDA’s decision in this matter.

Sincerely,

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Center for Science in the Public Interest