

ISSC 2009 Biennial Meeting
October 17 – 23, 2009 Manchester, New Hampshire
Committee Report

Committee Name :	Reciprocity
Chairperson:	Kirk Wiles
Date of Meeting:	Conference calls on 8/5/09 and 9/21/09
Roster:	Guilbeau, David Begos, Kevin Dewey, Bill Guichard, Maryanne Hastback, Bill Howell, Lori Shepherd, Sandy
Charge:	Determine if the State of Virginia violated reciprocity during the Mississippi illness outbreak and recall.
Findings:	<p>The committee met by conference call on 8/5/09. After exchanges between parties, the Committee requested that the State of Mississippi submit in writing to the Committee the specific actions of Virginia that violated Procedure XVII, Reciprocity of the ISSC Constitution and By Laws. The Committee requested that the State of Virginia be allowed to respond in writing to the allegations. Mississippi sent their document and Virginia responded. Mississippi responded to the reply of Virginia. All of the documents are included as attachments.</p> <p>A conference call meeting of the Committee occurred on 9/21/09. The following motion was passed by the Committee: “Virginia violated reciprocity by failing to notify the ISSC of its actions in relation to Procedure XVII, Section 1.”</p> <p>A second motion was made and passed as follows: “This committee recognizes that Virginia took actions intended to protect public health; while still violating Procedure XVII, Section 1. Therefore the committee recommend Procedure XVII be revised to clarify actions and communication necessary and appropriate in emergency situations.”</p> <p>A third motion was made and was not passed by the Committee: “That Virginia also violated reciprocity by calling for the mandatory recall of Mississippi oysters and by requiring Mississippi to provide excess documentation on shucked shellfish product.”</p>
Conclusions:	The Reciprocity Committee concluded that Virginia violated reciprocity by failing to notify the ISSC of its actions in relation to Procedure XVII, section 1.
Recommendations:	“This committee recognizes that Virginia took actions intended to protect public health; while still violating Procedure XVII, Section 1. Therefore the committee recommend Procedure XVII be revised to clarify actions and communication necessary and appropriate in emergency situations.”
Additional Information:	
Recorder:	
Approved by:	Kirk Wiles



STATE OF MISSISSIPPI

Haley Barbour
Governor

MISSISSIPPI DEPARTMENT OF MARINE RESOURCES

William W. Walker, Ph.D., Executive Director

To: Reciprocity Work Group Members

From: Dale Diaz, Office of Marine Fisheries Director

P.D.

Date: August 20 2009

Re: Virginia's alleged breach of Procedure V. Guidelines and Procedure XVII. Reciprocity

At the end of the Reciprocity Work Group teleconference on August 4, 2009, the Mississippi Department of Marine Resources was requested to provide the Reciprocity Work Group with a brief letter identifying those parts of the Interstate Shellfish Sanitation Conference's (ISSC) Constitution, Bylaws, and Procedures that was allegedly violated by Virginia when on March 21, 2009 Virginia issued a total recall of shellfish harvested between February 24 and March 17, 2009 from Mississippi's "section 2C". The following is submitted in response to the August 4 request.

The ISSC's Constitution, Bylaws and Procedures provide in Procedure V. Guidelines that "Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the National Shellfish Sanitation Program (NSSP)." Mississippi's shellfish program is in compliance with the NSSP and was in compliance on March 21, 2009 when Virginia unilaterally ordered a mandatory recall of all Mississippi oysters harvested from "section 2C".¹

The ISSC's Constitution, Bylaws and Procedures state in Procedure XVII. Reciprocity that "Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements." Virginia's action on March 21, 2009 in recalling Mississippi oysters harvested from "section 2C" required producing states to provide documentation on shucked shellfish product above and beyond the requirements of the NSSP and ISSC agreements.²

¹ At the time that Virginia ordered a total recall even Tennessee, the state that had reported a possible biological connection, had not determined that such a drastic step was necessary. If Virginia was of the opinion that Mississippi was not in compliance with the NSSP, they should have initiated a complaint in accordance with procedures of the ISSC.

² Florida complained of this additional burden in David Heil's email of March 23, 2009 to the ISSC. The NSSP Model Ordinance does not require on either labels or shipping documents for shucked product the harvest area or

The ISSC's Constitution, Bylaws and Procedures provides in Procedure XVII. Reciprocity Section 1. Notification and Consultation:

A state, prior to taking an action that may fail to meet the definition of 'reciprocity,' must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take action. The state should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that state;
- The potential effect on the public health in other states;
- The potential economic impact on states;³
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I requirements relating to uniformity and the importance of operating within a collective framework.

It is clearly the intent of the ISSC in Procedure XVII Section 1 to require consultation between a state and the ISSC's Executive Board before a state takes any action contrary to the provisions of the NSSP or the ISSC constitution. The requirement for consultation and justification prior to taking an action that affects a member state is not restricted by a particular time of day nor day of the week. Virginia failed to consult with the ISSC Executive Board prior to taking their unilateral action on March 21, 2009 and no justification was provided for ordering a total recall of oysters harvested from Mississippi's "section 2C".⁴

Unilateral action of another ISSC member state in 2003 resulted in amendments strengthening the reciprocity provisions of the ISSC's Constitution, Bylaws, and Procedures. The importance of uniformity and consultation to the participants is clear. It is also clear that Virginia failed to comply with the reciprocity provisions of the ISSC's Procedure XVII.⁵

Mississippi requests that it be allowed to review and respond to any response to this memorandum submitted by Virginia prior to any decision by the Reciprocity Work Group.

date of harvest (see Chapter X at .05, .06 and .08). Virginia via Bob Croonenberghs email of March 22, 2009 required from producing states documentation on the origin of shellstock beyond that required by the NSSP.

³ Mississippi has not endeavored to calculate the potential costs of the recall ordered by Virginia on March 21, 2009. However, any recall would have an adverse impact on producing states and the recall of the oysters harvested between February 24 and March 17, 2009 from Mississippi's growing area 2C has resulted in the submission of over One Million Dollars in claims to the Mississippi Department of Marine Resources.

⁴ The fact that it was late on a Friday afternoon is not justification for ignoring the provisions of Procedure XVII. All member states are required to provide contact information so that consultation and coordination may take place outside of normal business hours including weekends and holidays. Even the following Monday there was no apparent attempt by Virginia to comply with Procedure XVII.

⁵ Virginia may be inclined to point to the eventual recall of the oysters harvested from Mississippi's area 2C growing waters. Mississippi asserts the subsequent action to recall the oysters is immaterial to whether Virginia's actions on March 21, 2009 violated the provisions of the ISSC's Constitution, Bylaws, and Procedures. The ultimate decision by Mississippi to issue a recall was a close one that was made after consultation with the FDA and in accordance with the policies and procedures of the ISSC. In hindsight, the necessity of ordering a total recall is arguable but is beyond the task of this work group and not relevant to the charges at hand.



COMMONWEALTH of VIRGINIA

Department of Health

DIVISION OF SHELLFISH SANITATION

109 Governor Street, 6th Floor
Richmond, Virginia 23219

Ph: 804-864-7487
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August 31, 2009

To: ISSC Reciprocity Committee

From: Robert E. Croonenberghs, PhD, Director 

Subject: Virginia's Emergency Recall of Mississippi's Potentially Contaminated Oysters

The Virginia Department of Health (VDH) has received the Mississippi Department of Marine Resources' (MDMR) memorandum of August 20, 2009 concerning reciprocity issues in connection with VDH's March 20, 2009 emergency recall of potentially contaminated oysters from MS Area 2C. In response VDH presents the following information and requests that the Committee also consider VDH's April 27, 2009 letter to Ken Moore for further background information.

MDMR asserts in the second paragraph of their memorandum that on March 21, 2009, its actions were in compliance with the requirements of the National Shellfish Sanitation Program (NSSP) and therefore all states should have accepted its product. However, MDMR was not in compliance with Chapter II. @01.H(2) of the NSSP which requires a state to close a growing area and "Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology..." VDH became aware of information on Friday, March 20, 2009 of PCR analytical results that conclusively tied a January 2009 harvest from the same growing area to illness. Under these circumstances, MDMR issued a press release saying that the oysters that they were shipping could indeed be contaminated with norovirus. MDMR recommended that their oysters be cooked, a procedure that is of questionable effectiveness, is an unacceptable approach under the Seafood HACCP Rule, and is not recognized by any provision of the NSSP as an acceptable method for dealing with potentially contaminated shellfish.

Given our understanding of these facts, VDH realized at a late hour that we could be facing a public health emergency. In an emergency, the only responsible way to act is to resolve it as quickly as possible. Had VDH delayed its recall and spent a few days contacting Executive Board members, more time would have elapsed that could have lead to widespread illness. Indeed, the first paragraph, entitled Procedure XVII, allows for this emergency exception, "The ISSC recognizes that states should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish."

The notification process contained in Section 1 is so involved that it logically cannot apply to immediate emergencies, but only to chronic situations, such as the case of a state finally deciding that it cannot allow any more oysters with *Vibrio vulnificus* concerns into its borders. A chronic public health emergency is not one that is likely to rapidly deteriorate, and thus deserves Executive Board review beforehand.

Once VDH came to the realization that it could not ethically import these oysters harvested from MS Area 2C, it became necessary to know whether shucked oysters came from that area as well. The request for harvest area information in my email of March 22, 2009 was necessary as part of the recall process. It was requested in the spirit of state shellfish programs cooperating in a recall. Most likely, few shipments were involved.

MDMR raises the issue of why VDH did not contact the ISSC after issuing the recall. The stated purpose in Procedure XVII of contact with the Board is to “take into account the views of the ISSC prior to a decision to take the action.” Once VDH took its action, everyone involved with the recall was aware and it was no longer necessary to contact the Board.

While VDH is well aware of the unusual nature of this recall, we believe that the recall was warranted as there was a public health emergency and our primary responsibility as an agency is to protect the public health. This often requires swift action. We understand the need and requirements of both the ISSC and the NSSP and we believe that we complied with these to the greatest extent possible given the nature of the public health threat the people of Virginia potentially faced.



COMMONWEALTH of VIRGINIA

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April 27, 2009

Mr. Ken Moore, Executive Director
Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223

Dear Mr. Moore,

The Mississippi Department of Marine Resources (MDMR) has asked you to evaluate whether the Virginia Department of Health's March 20, 2009 recall of oysters harvested from Mississippi growing area 2C is consistent with the constitution of the Interstate Shellfish Sanitation Conference (ISSC). I am writing to explain to you and the Executive Board of the ISSC the reasons for our action.

On March 17, 2009 the Tennessee Department of Health finalized and issued an epidemiological report that implicated Mississippi's growing area 2C in an outbreak of Norovirus due to oysters harvested on February 24, 2009. The Mississippi Department of Marine Resources (MDMR) responded by closing the harvest area on March 17th, but issued a recall only for oysters harvested on February 24th from the area. In a public service notice, the MDMR stated that "it is possible that suspect oysters from the designated area are still available in other retail and food service settings." This notice then indicated that "cooking destroys the virus" and that "consumers can continue to enjoy oysters in many cooked preparations" by following the ensuing advice.

VDH personnel began the recall of the one-day's production on March 18th, and then contacted the MDMR on March 19th concerning the issues surrounding the recall. We were concerned that the MDMR had substituted cooking advice in place of recalling the remaining 20-days production. The National Shellfish Sanitation Program (NSSP) requires a minimum 21-day closure of a growing area when the illness "is consistent with viral etiology." The reason for the 21-day closure is to acknowledge the need for both the growing waters and the shellfish to purge the viral particles. Initiating a closure three weeks after the harvest date of shellfish implicated in an outbreak, with only a one-day recall of product, appeared to violate the NSSP minimum requirement and did not comport with our understanding of estuarine processes.

The VDH was aware that the MDMR assessed the outbreak associated with the Tennessee restaurant as a problem that probably originated in Tennessee, however VDH was required to consider other information that the MDMR appeared to downplay. This information linked an earlier

outbreak at that same Tennessee restaurant (due to a January harvest) with a separate illness cluster in Mississippi. PCR analyses conducted by FDA revealed identical Norovirus nucleotide sequences in stool from a customer of the Tennessee restaurant, in unopened shell oysters in Tennessee from area 2C, and in stool from a person that ate oysters from area 2C while in Mississippi. This meant that the outbreak associated with the January harvest was highly likely due to growing area contamination, and that the outbreak associated with the February harvest was more likely than not due to growing area contamination (which ultimately appears to be the case). Unraveling this information took some time during the week, and the VDH was waiting to hear whether FDA would determine that MDMR had failed to implement effective actions to protect public health and would issue a public warning.

By Friday afternoon the State Health Commissioner convened a team consisting of personnel from epidemiology, restaurant inspections, shellfish sanitation, emergency preparedness and response, media relations, etc. to assess the situation. We felt an obligation to issue a public notice prior to the weekend, in order to alert the public to the potential presence of contaminated oysters in the market and restaurants. As there is no definitive research on how much heat is needed to inactivate Norovirus in oysters, VDH did not believe that a cooking advisory would be sufficient to protect the citizens of the Commonwealth. Furthermore, any cooking advisory would have to apply to all shucked oysters since most shucked oyster containers do not display growing area information. Due to our concerns that the NSSP minimum requirement for closure was not being followed and our desire and obligation to protect public health, VDH issued a recall for the oysters harvested from February 24, 2009 through March 17, 2009.

VDH initiated its recall of Mississippi's approved product under the emergency provision of Procedure XVII of the Constitution of the ISSC, which states "The ISSC recognizes that states should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish". While Section 1 of this Procedure provides a format for a state to petition the Executive Board to consider the issue of whether one state can exclude another state's approved product, this format is too involved and not designed to handle the emergency situation that we believe existed in this situation. We plan to submit a proposal to the ISSC to provide for a streamlined mechanism in the case of an emergency. We will also ask the Conference to address whether cooking is an acceptable alternative to recalling potentially contaminated product.

VDH does not wish to find itself in this position again of having to initiate a recall for potentially contaminated shellfish that have been approved for marketing by another state. We do not believe that a state can place the responsibility on the consumer to correct potential food contamination rather than to recall that food from the market.

Thank you for the opportunity to explain our actions and intentions to you and the Executive Board.

Sincerely,



Robert E. Croonenberghs, PhD, Director
Division of Shellfish Sanitation



STATE OF MISSISSIPPI

Haley Barbour
Governor

MISSISSIPPI DEPARTMENT OF MARINE RESOURCES

William W. Walker, Ph.D., Executive Director

To: Reciprocity Work Group Members

From: Dale Diaz, Office of Marine Fisheries Director *D.D.*

Date: 9/7/2009

Re: Virginia's alleged breach of Procedure V and Procedure XVII Reciprocity

The Mississippi Department of Marine Resources (MDMR) appreciates the opportunity to review and comment on the August 31, 2009 letter submitted to the Work Group by the Virginia Department of Health (VDH).

The VDH letter of August 31 makes plain that there is a problem with the interpretation of the provisions of the Interstate Shellfish Sanitation Conference's (ISSC) Constitution, Bylaws, and Procedures and the National Shellfish Sanitation Program (NSSP). The MDMR interprets ISSC Procedure XVII as requiring consultation with the ISSC Executive Board whenever a state proposes or takes action "that may fail to meet the definition of reciprocity". VDH's apparent position is that it may unilaterally act without consultation whenever it perceives the need to do so and, if it acts without prior consultation, no subsequent notification to the ISSC Executive Board is required. Beyond that, VDH asserts that it has the unilateral authority to declare another state's program to be in non-compliance with the NSSP.¹

The MDMR asserts that the ISSC requires consultation and cooperation among the members. On the date that VDH unilaterally ordered a total recall of all oysters harvested from Mississippi growing area 2C, the MDMR had already closed the area in question, ordered a recall of oysters harvested on February 24, and had issued an advisory to thoroughly cook all oysters harvested on and after February 25.² The actions taken by the

¹ VDH asserts in the letter of August 31 that "MDMR was not in compliance with Chapter II. @01.H(2) of the NSSP". The referenced section requires the closure of an implicated reef for a period of twenty-one days. The MDMR had in-fact closed the reef on March 17, 2009.

² As for the advisory to cook the oysters harvested from Mississippi growing area 2C, the MDMR has previously pointed out that there are numerous authorities, including the Virginia Department of Health's website (<http://www.vdh.virginia.gov:80/epidemiology/factsheets/Norovirus.htm>), that advocate cooking shellfish to destroy contamination from norovirus (Current as of 9-4-2009). A non-exhaustive list includes: <http://www.healthcenter.vt.edu/pdf/MCInfoSheet-norovirus.pdf>, Virginia Tech Schiffert Health Center has issued a publication advising the public that cooking oysters can kill the norovirus;

MDMR were reasonable and prudent at the time and were consistent with other recalls taken by other members of the ISSC.³

The actions of VDH on March 21, 2009, were not justified and violated ISSC Procedure V. and the intent of ISSC Procedure XVII.

<http://www.extension.umn.edu/extensionnews/2007/norovirus.html>, University of Minnesota Extension (Norovirus is killed by cooking. Use a food thermometer to make certain foods reach the recommended internal cooking temperature); <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01579.html>, (A FDA News Release for TX oysters); <http://www.health.gov.nf.ca/health/publications/ehp/pdf/Norovirus.pdf>, (Newfoundland Labrador - Health and Community Services); <http://www.foodsafety.gov/~fsg/f07virus.html>, (FDA Center for Food Safety and Applied Nutrition, USDA Food Safety and Inspection Service, Partnership for Food Safety Education) Cooking oysters completely to kill the virus; <http://www.nzfsa.govt.nz/processed-food-retail-sale/fact-sheets/oysters.htm>, (New Zealand) Handling Potentially Contaminated Oysters; http://www.nihs.go.jp/hse/food-info/microbial/noro/Noro_riskprofile.pdf, RISK PROFILE OF NOROVIRUS IN BIVALVE MOLLUSCAN SHELLFISH; http://www.health.nt.gov.au/library/scripts/objectifyMedia.aspx?file=pdf/9/42.pdf&siteID=1&str_title=Norovirus.pdf, Australia Centre for Disease Control (Cooking oysters thoroughly before eating them will reduce the risk of infection); <http://www.nkyhealth.org/mx/hm.asp?id=norovirusfs>, Northern Kentucky Independent District Health Department - Properly cooking oysters before eating; and <http://www.idph.state.il.us/public/hb/hbnorovirus.htm>, Illinois Department of Public Health (Carefully wash fruits and vegetables, and steam oysters before eating them).

³ For example, in February 2007, twenty-five people in Maryland became sick with Norovirus after consuming oysters harvested from San Antonio Bay, TX. The individuals consumed the oysters the weekend of February 9-11, 2007. The Texas Department of Health Services closed the reef on February 24 and the FDA issued an advisory for consumers to “avoid eating *raw* oysters harvested from this area after February 1, 2007.” (Emphasis added). The FDA advisory also provided “Cooking destroys the virus, eliminating the risk of illness for both healthy and immunocompromised individuals.” See <http://www.in.gov/isdh/24189.htm> for a copy of the FDA advisory.