

 <p><b>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</b></p>	<input type="checkbox"/> Growing Area <input checked="" type="checkbox"/> Harvesting/Handling/Distribution <input type="checkbox"/> Administrative
Submitter	ISSC Executive Office
Affiliation	Interstate Shellfish Sanitation Conference
Address Line 1	209 Dawson Road
Address Line 2	Suite 1
City, State, Zip	Columbia, SC 29223-1740
Phone	803-788-7559
Fax	803-788-7576
Email	issc@issc.org
Proposal Subject	Notices of Illness Outbreaks, Recalls and Closures
Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish Section II. Chapter II. Risk Assessment and Risk Management @.01 Outbreaks of Shellfish-Related Illnesses
Text of Proposal/ Requested Action	<p>@.01 Outbreaks of Shellfish-Related Illness</p> <p>B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:</p> <ol style="list-style-type: none"> <li>(1) <u>Notify the FDA Regional Shellfish Specialist that a shellfish related outbreak has occurred.</u></li> <li><del>(2)</del> Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.</li> <li><del>(3)</del> Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.</li> </ol> <p>C. When the investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:</p> <ol style="list-style-type: none"> <li>(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;</li> <li>(2) Notify <del>receiving states</del>, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;</li> <li><del>(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and</del></li> <li><del>(4)</del> Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.</li> <li><u>(4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.</u></li> <li><u>(5) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.</u></li> </ol>

	<p>D. When the investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:</p> <ul style="list-style-type: none"> <li>(1) Notify <del>receiving states,</del> the ISSC and the FDA Regional Shellfish Specialist of the problem; and</li> <li>(2) Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.</li> <li><u>(3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.</u></li> <li><u>(4) The ISSC will notify States and FDA Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.</u></li> </ul>
<p>Public Health Significance</p>	<p>The proposed language in Section B. would ensure that FDA is immediately aware of shellfish related outbreaks. The proposed language changes in Section C. would more clearly outline the responsibility associated with notification to FDA and States. Currently notification requirements are not included for recalls associated with post-harvest contamination. Additionally, there are no requirements for notification to States that are not identified as a State receiving recalled product. It is important that all States be notified of recalls. In many cases the complete list of States cannot be determined by identifying the initial dealers. The proposed change would also establish an inventory of closures and recalls. Without an inventory it is difficult to assess program trends.</p>
<p>Cost Information</p>	