

<b>Proposal Subject</b>	Shellfish Sanitation Plant Element Evaluation Criteria
<b>Specific NSSP Guide Reference</b>	ISSC Constitution, Bylaws, and Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Elements Section 6. Subdivision b. Subdivision iv. (NEW)
<b>Text of Proposal/ Requested Action</b>	<p>Add new Subdivision iv. as follows:</p> <p><b><u>iv. Shellfish sanitation program element compliance will be based on the following criteria:</u></b></p> <p><b><u>(a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.</u></b></p> <p><b><u>(b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.</u></b></p> <p><b><u>(c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.</u></b></p> <p><b><u>(d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the state.</u></b></p> <p><b><u>(e) All critical deficiencies have been addressed by the state inspector in accordance with the Guide for the Control of Molluscan Shellfish.</u></b></p>
<b>Public Health Significance</b>	These criteria will be helpful to both the USFDA and States in the state evaluation process.
<b>Cost Information (if available)</b>	No costs associated with this program addition.
<b>Action by 2005 NSSP Evaluation Criteria Committee</b>	<p>Recommended adoption of Proposal 05-310 as amended by the NSSP Evaluation Criteria Committee, the submitter.</p> <p><b><u>iv. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This</u></b>  <del>shellfish sanitation</del> program element compliance will be based on the following criteria:</p> <p>(a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.</p> <p>(b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.</p> <p>(c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.</p> <p>(d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the state.</p> <p>(e) All critical deficiencies have been addressed by the state inspector in accordance with the Guide for the Control of Molluscan Shellfish.</p>
<b>Action by 2005 Task Force III</b>	Recommended adoption of the recommendations in the NSSP Evaluation Criteria Committee report with an effective date of October 1, 2004.
<b>Action by 2005 General Assembly</b>	Adopted recommendation of 2005 Task Force III.

**Action by USFDA**

FDA concurs with adoption of the five evaluation criteria for identifying state programs whose plant processing element is seriously out of compliance with the NSSP. FDA recommends that the ISSC continue with efforts to develop additional criteria that may be used to define when a state program element is sufficiently out of compliance as to pose a public health risk. In particular, criteria are needed that focus on the in-field component of the FDA evaluation process, i.e. criteria to be used during the plant visit component of FDA's evaluation process. The criteria adopted by the 2005 Conference are more specific to the administrative aspects of a state's plant sanitation element. These criteria are examined as part of the central file review of a state program evaluation. Criteria that focus on the in-field component of the evaluation are also needed. New criteria should consider the distinction between sporadic plant deficiencies and those of an egregious and chronic nature that are indicative of systemic plant sanitation and safety problem.