

<b>Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting</b>		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
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Proposal Subject	Changes to Procedure for Evaluation of Shellfish Sanitation Program Elements.	
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Program Elements	
Text of Proposal/ Requested Action	<p>Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum:</p> <p>Subdivision a. Evaluation of growing area classification;</p> <p>Subdivision i. Records audit of sanitary survey;</p> <p>Subdivision ii. Bacteriological standards;</p> <p>Subdivision iii. Growing area classification;</p> <p>Subdivision iv. Marine Biotoxin control;</p> <p>Subdivision v. Marinas.</p> <p>Subdivision b. Evaluation of shellfish plant inspection program;</p> <p>Subdivision i. Records audit of past shellfish processing facility inspections;</p> <p>Subdivision ii. Direct observation of current shellfish processing facility conditions;</p> <p>Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.</p> <p>Subdivision 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 program element compliance will be based on the following criteria:</p> <p>Subdivision (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.</p> <p>Subdivision (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>Subdivision (c) Where compliance</p>	

		<p>schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.</p> <p>Subdivision (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>Subdivision (e) All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.</p> <p>Subdivision v. Plant Evaluation Criteria</p> <p>Subdivision (a) Legal Authority – Chapter VIII. @ .01 A. (2) (c). The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ .02. [Critical]</p> <p>Subdivision (b) Initial Certification – Chapter I @ .02 B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below: HACCP requirements:  <ul style="list-style-type: none"> <li>(i) A HACCP plan accepted by the Authority</li> <li>(ii) No critical deficiencies;</li> <li>(iii) Not more than 2 key deficiencies;</li> <li>(iv) Not more than 2 other deficiencies.</li> </ul> Sanitation and additional Model Ordinance Requirements:  <ul style="list-style-type: none"> <li>(i) No critical</li> </ul> </p>
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		<p>deficiencies;</p> <p>(ii) Not more than 2 key deficiencies;</p> <p>(iii) Not more than 3 other deficiencies.</p>
	Subdivision (c)	<p>Inspection frequency – Chapter I @ 02 F and G. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.</p>
	Subdivision (d)	<p>Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.</p>
	Subdivision (e)	<p>Follow-Up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.</p>
	Subdivision (f)	<p>Deficiency Follow-up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.</p>
	Subdivision (g)	<p>In-Field Plant Criteria. The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:</p> <p>(i) Shucker/packers and repackers HACCP requirements:</p> <p>a. A HACCP plan</p>

		<p>accepted by the Authority;</p> <p>b. No critical deficiencies;</p> <p>c. Not more than 4 key deficiencies;</p> <p>d. Not more than 4 other deficiencies.</p> <p>Sanitation and additional Model Ordinance Requirements</p> <p>a. No critical deficiencies <u>except when the State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility;</u></p> <p>b. Not more than 4 key deficiencies;</p> <p><del>e. Not more than 4 other deficiencies.</del></p> <p>(ii) Shellstock shippers and reshippers HACCP requirements:</p> <p>a. A HACCP plan accepted by the authority;</p> <p>b. No critical deficiencies;</p> <p>c. Not more than 3 key deficiencies;</p> <p>d. Not more than 3 other deficiencies.</p> <p>Sanitation and additional Model Ordinance Requirements</p> <p>a. No critical deficiencies <u>except when the</u></p>
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	<p style="text-align: right;"><u>State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility;</u></p> <p>b. Not more than 3 key deficiencies; <del>e. Not more than 5 other deficiencies.</del></p> <p>Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria</p> <p>Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations:</p> <p>(i) Conformance: The program is in compliance with all of the criteria listed above.</p> <p>(ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with key <del>or other</del> compliance items in Procedure XV. Section 6. Subdivision (b) Sub-division (v) (g).</p> <p>(iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (a), but, does not meet the criteria in Procedure XV.</p>
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		<p>Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with key <del>or other</del> compliance items Procedure XV.</p> <p>Section 6. Subdivision (b) Subdivision (v) (g).</p> <p>(iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV.</p> <p>Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV.</p> <p>Section 6. Subdivision (b) Subdivision (v) (g).</p>
	<p>FDA will follow the current compliance program for communication with the State agencies.</p> <p>Subdivision c. Evaluation of shellfish laboratories;</p> <p>Subdivision i. Records audit of laboratory operations;</p> <p>Subdivision ii. Direct observation of current laboratory operating conditions;</p> <p>Subdivision iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.</p> <p>Subdivision d. Evaluation of shellfish growing area patrol;</p> <p>Subdivision i. Records audit of past patrol activities;</p> <p>Subdivision ii. Direct observation of current patrol activities;</p> <p>Subdivision iii. Information collection from the Authority and other pertinent sources.</p>	
Public Health Significance	<p>Current Infield Plant Criteria automatically “fails” a plant even if the critical deficiency is address and corrected. This puts a plant in non-compliance but still operating which is inconsistent with the evaluation of deficiency follow-up in Subdivision v (f).</p> <p>States are deemed in compliance when evaluating deficiency follow-up when critical</p>	

	<p>deficiencies have been addressed. During a plant inspection, the professional discretion of the inspector is used to determine the severity of the critical deficiency. In some cases a critical deficiency that is addressed and corrected at the time of inspection allows the plant to legally continue to process and sell product. Critical deficiencies that are addressed and corrected at the time of the infield Plant Sanitation Element should be consistent with this.</p> <p>Deficiencies with a criticality code of “Other” vary widely in public health significance and in many cases may be the result of normal wear or use during the operating season. This is especially true with items in Item 17; Plants and Grounds, and Item 21; Equipment Condition, Cleaning, Maintenance and Construction of Non-Food Contact Surfaces. Many of these “other” deficiencies are addressed prior to re-certification for the following season.</p>
Cost Information	No cost to states or industry.
Action by 2013 Task Force III	Recommended referral of Proposal 13-308 to the NSSP Evaluation Criteria Committee
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-308.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-308.