| **Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting** | ☐ Growing Area<br>☐ Harvesting/Handling/Distribution<br>☒ Administrative |
|---|---|

| | |
|---|---|
| Submitter | Ken Moore<br>Patti Fowler |
| Affiliation | Interstate Shellfish Sanitation Conference(ISSC)<br>North Carolina Division of Marine Fisheries |
| Address Line 1 | 209 Dawson Road<br>PO Box 769 |
| Address Line 2 | Suite 1 |
| City, State, Zip | Columbia, SC 29223<br>Morehead, NC 28557 |
| Phone | 803-788-7559<br>252-808-8147 |
| Fax | 803-788-7576 |
| Email | issc@issc.org<br>patti.fowler@ncdenr.gov |
| Proposal Subject | Unresolved Issue Procedure |
| Specific NSSP Guide Reference | ISSC Constitution, Bylaws, and Procedures<br>Procedure IX. Procedures for Handling Complaints and Challenges Regarding the Adequacy of Certification Controls |
| Text of Proposal/ Requested Action | Section 2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:<br><br>Subdivision a. FDA shall provide written notification to the state shellfish control authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.<br>Subdivision b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.<br>Subdivision c. When a state does not disagree with FDA findings, but does disagree with an FDA report, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days. |

| | |
|---|---|
| | Subdivision d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.<br>Subdivision e. If FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), FDA shall notify the ISSC Executive Director of~~or if the state disagrees with FDA's findings or response, it shall be considered~~ an unresolved issue. If the State disagrees with FDA's findings or response, the State may pursue one of the following actions:<br>Subdivision i. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or<br>Subdivision ii. The State shall notify the ISSC Executive Director of an unresolved issue.<br>Subdivision f. Upon notification of an unresolved issue, ~~FDA or the state shall notify~~ the ISSC Executive Director ~~who~~ shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product. |
| Public Health Significance | |
| Cost Information | |