

	<p>Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting</p>	<p>1. a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative</p>
2. Submitter	US Food & Drug Administration (FDA)	
3. Affiliation	US Food & Drug Administration (FDA)	
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10. Proposal Subject	Emergency Conditions re-opening studies.	
11. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification A.(5)(c)(i).	
12. Text of Proposal/ Requested Action	<p>(i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. <u>When pathogens are of concern, S</u>studies establishing sufficient elapsed time shall document the interval necessary for reduction of <u>contaminant coliform</u> levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the <u>Such coliform studies</u> may establish criteria for reopening based on coliform levels in the water. <u>When poisonous or deleterious substances are the concern, studies shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation;</u> or</p>	
13. Public Health Significance	<p>National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, Section IV Guidance Documents, Chapter II Growing Areas, .08 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood contains target levels for many poisonous or deleterious substances. Target levels for other substances can be established through risk evaluation. The 2010 Deepwater Horizon crisis provides an example of how emergency conditions involving poisonous or deleterious substances are addressed in practice. Levels of concern were established through risk evaluation then areas were re-opened based on determining that contaminant levels were below levels of concern rather than based on comparisons between pre and post closure levels.</p>	
14. Cost Information	<p>Cost would potentially be reduced because studies to compare post closure levels of poisonous or deleterious substances to pre closure levels would no longer be required.</p>	