Proposal No. 2 7 - 2 1 8

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. X Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Clarify that when post-harvest issues are ruled out, the growing area should be deemed to be the source of the issue
10. Specific NSSP Guide Reference	Section II Model Ordinance - Chapter II. Risk Assessment Risk Management @.01 Outbreaks of Shellfish-Related Illness
11. Text of Proposal/ Requested Action	C. When the Authorities determine that the outbreak is not the result of a post-harvest contamination problem or illegal harvesting from a closed area, the Authority shall deem the growing area(s) to be the source of the contamination and determine if the outbreak is from a single source or multiple sources. (1) When the Authority determines that a single source outbreak has occurred, the Authority shall: (a) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; (b) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;…. D. When the appropriate Authorities determine that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area occurred shall:… E. When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall:… F. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:… G. When the growing area is ~~determined~~ deemed to be the source of the contamination ~~problem~~, either through the result of growing area investigation or when no illegal harvesting from a closed area or post-harvest contamination problems issues are identified as described in @.01 C., the Authority shall: (1) Place the growing area in the closed status until: (a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:…
12. Public Health Significance	Current language in Chapter II. @.01 is unclear that once post-harvest contamination problems or illegal harvesting from a closed area are ruled out as potential sources of contamination leading to an illness outbreak that the growing area should be considered the source of contamination. While growing area

	investigations often do not uncover issues, the potential for small contamination events (e.g., overboard discharge) generally cannot be ruled out due to the time elapsed from illness notification and growing area investigation. Routine growing area sampling may not identify these issues due to their limited nature (potentially small area impacted for a short time frame). The proposed language is to clarify the existing requirements for the Authority to respond to outbreaks for which no post-harvest issues or illegal harvest are identified.
13. Cost Information	None.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD