Proposal No. 2 7 - 2 2 1

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☒ 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
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6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Notification of precautionary closure
10. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. @.01 E.
11. Text of Proposal/ Requested Action	Chapter II. @.01 Outbreaks of Shellfish -Related Illness 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: (1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post-harvest contamination, or mishandling, or harvested from a closed area, the suspected growing area can be reopened. (2) Notify the ISSC and the FDA Shellfish Specialist in writing of the precautionary closure. ~~(2)~~ (3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate. ~~(3)~~ (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.
12. Public Health Significance	There is no definition in the Model Ordinance for precautionary closed status. The only real difference between closed status for a growing area and precautionary closed status in the event of shellfish-related illness is the reopening criteria. Precautionary closed status should be treated the same as closed status, including making the appropriate notifications.
13. Cost Information	There would be no cost to the industry or Authority related to this proposal.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD