Proposal No. 2 7 - 1 0 8

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
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9. Proposal Subject	Clarification of illness investigation timing and precautionary growing area closure during illness investigation
10. Specific NSSP Guide Reference	Section II, Chapter II, @.01 B (2) and @.01 E (1-3)
11. Text of Proposal/ Requested Action	Section II, Chapter II, @.01 B (2) B. When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall: (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) Within twenty-four (24) hours initiate the investigation to determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source state. (3) When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall: (a) 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. (b) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate. (c) 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. AND Section II, Chapter II, @.01 E (1-3) ~~(3) 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) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate.~~ ~~(3) 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	The proposed change clarifies the distinction between precautionary growing area closure and growing area closures during the initial phase of an illness investigation and does not reduce public health protection. Existing language in the 2023 MO requires determination of the cause(s) of shellfish-related illness within 24-hours ("…Authorities shall: Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting…" (Section II, Chapter II, @.01 B (2)); and then in Section II, Chapter II, @.01 C requires that, lacking initial evidence of post-harvest contamination, etc., implicated growing areas be immediately placed in the closed status, with a series of actions required to reopen the closed area(s) outlined in Section II, Chapter II, @.01 F. However, in Section II, Chapter II, @.01 E current MO language allows implicated growing area(s) to immediately placed in the precautionary closed status *if the Authority can not make an illness determination within 24 hours* (Section II, Chapter II, @.01 E(1)). The proposed language would require that the Authorities initiate illness investigation within 24 hours and place implicated growing area(s) into the precautionary closed status during that investigation. If subsequent investigation identifies non-growing area causes of contamination (post-harvest handling, illegal harvest, etc.) then precautionarily closed areas can be reopened immediately, the same as stipulated in existing 2023 MO language in Section II, Chapter II, @.01 E (1). If the investigation identifies the growing area as the cause of illness, then the implicated growing area(s) will be changed from the precautionary closed to the closed status immediately upon that determination, with the reopening criteria in Section II, Chapter II, @.01 F applied prior to reopening the implicated closed area(s). The proposal also seeks to move unmodified language of Section II, Chapter II, @.01 E forward so that it becomes Section II, Chapter II, @.01 B (3) (a-c) to clarify the timing of precautionary closure of implicated growing area(s) during the investigatory period. No language changes are proposed for Section II, Chapter II, @.01 E of the current MO; only the above-described relocation of that text for clarity is proposed.
13. Cost Information	No additional costs are associated with the proposed changes.
14. Changes Needed to Guidance (if proposed change is adopted)	Guidance in Section IV. Guidance Documents – Chapter II Risk Assessment and Risk may need minor revision to reflect the distinction between a precautionary closure during the period of investigation versus a growing area closure if the investigation identifies the growing area is responsible for the illness.