Proposal No. 2 7 - 2 2 0

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
5. Address Line 2	
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 growing area closures and recalls due to outbreaks of shellfish-related illness
10. Specific NSSP Guide Reference	Section II Model Ordinance Chapter II. @.01 B. (1), C. (1) and @.01 D.
11. Text of Proposal/ Requested Action	Chapter II. @.01 Outbreaks of Shellfish-Related Illness 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) … C. …. (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 in writing ~~Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated~~ of the growing area closure; (c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products. (d) Transmit to the ~~ISSC and~~ FDA information identifying the dealers shipping the implicated shellfish. (e) In the case of recalls, the FDA will provide States with information identifying dealers receiving the implicated shellfish and dealers further distributing the implicated product; (f) ~~The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish.~~ Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall ~~information~~ notices. 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 are occurred shall: ~~(1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and~~ (1) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority. The recall shall include all implicated products. (2) ~~Inform~~Notify the ISSC and the FDA in writing of the recall. (3) Transmit to the ~~ISSC and~~ FDA information identifying the dealers shipping the implicated shellfish. (i) In the case of recalls, the FDA will provide States with information identifying dealers receiving the implicated shellfish and dealers further distributing the implicated product. (4) ~~The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify states with information identifying dealers shipping the implicated shellfish. Closure and~~ Recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of ~~closure and~~ recall ~~information~~ notices.
12. Public Health Significance	This section directs the Authority to make certain notifications when growing area closures and recalls are necessary to respond to incidents of shellfish-borne illness. It also places requirements on the ISSC and the FDA. Currently, the ISSC is not providing notification about dealers shipping the implicated product to states, so this proposal removes that requirement and clarifies that the FDA will make those notifications and provide further distribution information. In the case of shellfish-borne illness, it is imperative to notify states potentially receiving implicated product as quickly as possible so that product can be removed from commerce. It is more efficient for the FDA to collect distribution information and provide it to states than for the ISSC to do that activity. The role of the ISSC should be to post the closure and recall notices and make the membership aware of the issue. The FDA, through the Shellfish Specialists and other DSS staff are better equipped to assist the states in providing distribution information to impacted states. Additionally, some states are not able to provide specific dealer information and quantity of shellfish shipped due to state information sharing laws to a non-regulatory entity such as the ISSC. States routinely share this information with the FDA, and by taking the ISSC out of the notification chain, efficiency is increased allowing for more rapid 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