Proposal No. 2 7 - 1 1 0

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Chris Schillaci
3. Affiliation	East Coast Shellfish Growers Association (ECSGA)
4. Address Line 1	111 Myrtle Street
5. Address Line 2	
6. City, State, Zip	New Bedford, MA 02740
7. Phone	(401) 783-3360
8. Email	chris@ecsga.org
9. Proposal Subject	Consideration of Illnesses Among Non-Consumers of Shellfish in Outbreak Investigations
10. Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish, 2023 Revision. Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness, B. (new (3) and (4)), C. (2) (new (d)), and E. (1).
11. Text of Proposal/ Requested Action	Amend Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness, as follows. New language is shown in red double underline. Deleted language is shown in blue strikethrough. Existing text not shown is unchanged (indicated by ellipses). **1. Add new paragraphs B.(3) and B.(4):** B. When the state or local epidemiologist ... the appropriate Authorities shall: (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) 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 from a closed area. ... (3) The Authority, in consultation with the epidemiologist(s) in the state(s) in which the outbreak occurs, may determine that the outbreak is not attributable to shellfish when the investigation documents that: (a) Cases within the same illness cluster (the same event, establishment, or common exposure setting and time period) include one (1) or more persons who did not consume shellfish; (b) The illnesses among persons who did not consume shellfish are caused by, or are clinically consistent with, the same etiologic agent as the illnesses among persons who consumed shellfish and, where laboratory data are available, share the same genotype, strain, or sequence type; (c) The onset dates of the illnesses among persons who did not consume shellfish are consistent with exposure to a common source during the same exposure period and are not consistent with secondary (person-to-person) transmission from persons who consumed shellfish; and (d) The epidemiological evidence, including food histories and, where

	available, food-specific attack rates, identifies a source other than shellfish (such as an ill food worker, another food item, or environmental contamination) or does not support an association between illness and shellfish consumption. (4) When the Authority makes the determination described in B.(3): (a) Growing area closure and recall of shellfish are not required; (b) Any precautionary closure placed under Section C.(2) or Section E.(1) may be immediately lifted; (c) The Authority shall notify the FDA Shellfish Specialist and the ISSC of the determination and provide the supporting basis; (d) The Authority shall document the determination and supporting information in a written record in the central file; and (e) If additional information becomes available (e.g., additional cases, trace-back results, or laboratory results) that implicates shellfish, the Authority shall take the actions required in Sections C. through H. **2. Amend C.(2) by adding new item (d):** A specific growing area placed in a precautionary closed status under this section can be immediately re-opened when one (1) or more of the following conditions are met: (a) ... (b) ... (c) ... (d) The Authority has determined, in accordance with Section B.(3), that the outbreak is not attributable to shellfish. **3. Amend E.(1):** (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, or are not attributable to shellfish in accordance with Section B.(3), the suspected growing area can be reopened.
12. Public Health Significance	Section II, Chapter II @.01 establishes the actions an Authority must take once shellfish are epidemiologically associated with an outbreak, and Section E requires a precautionary closure whenever the growing-area determination cannot be completed within 24 hours. The Model Ordinance provides explicit off-ramps for outbreaks traced to post-harvest contamination, mishandling, or illegal harvest (Section D) and for multiple-source outbreaks (Section C.(2)), but it does not explicitly recognize one of the most informative findings in an outbreak investigation: persons in the same illness cluster who became ill but did not eat shellfish. Norovirus and other enteric outbreaks at events, restaurants, and catered functions frequently involve multiple menu items and ill food workers. When shellfish were served, early food histories can create an apparent association with shellfish even though non-consumers in the same cluster became ill with the same agent at the same time. Such cases point to a common source other than shellfish. Without clear authority in the Model Ordinance to act on this evidence, Authorities may feel

	obligated to close growing areas and initiate recalls that do not protect public health, while investigative resources are drawn away from identifying and controlling the actual source. The proposed language gives the Authority discretion, in consultation with the epidemiologist, to conclude that an outbreak is not attributable to shellfish, while building in safeguards that protect public health: Timing of onset: non-consumer cases must be consistent with a common-source exposure and not with secondary person-to-person spread, which commonly follows shellfish-borne norovirus outbreaks and would otherwise be misread as evidence against shellfish. Same agent: cases must share the same etiologic agent, and the same genotype or strain where laboratory data exist. Supporting epidemiology: food histories and attack rates must identify another source or fail to support a shellfish association. Transparency and reversibility: the determination must be documented and reported to the FDA Shellfish Specialist and the ISSC, and the Authority must resume closure and recall actions if new evidence implicates shellfish. This approach is consistent with the epidemiological principles already referenced in @.01 A (International Association for Food Protection, Procedures to Investigate Foodborne Illness) and with the existing reopening criteria in C.(2), which allow reopening based on consumption data and other relevant information provided by state investigators. It aligns shellfish control actions with the weight of the epidemiological evidence, reduces unnecessary closures and recalls, and helps focus outbreak response on the true source of illness.
13. Cost Information	No additional cost to Authorities is anticipated; the proposal uses information already collected during routine outbreak investigations. The proposal is expected to reduce costs to Authorities, harvesters, and dealers by avoiding closures, recalls, and associated sampling and reopening activities in outbreaks not caused by shellfish.
14. Changes Needed to Guidance (if proposed change is adopted)	No changes to the Guidance Documents (Section IV) are required.