Proposal No. 2 7 - 1 1 1

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
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9. Proposal Subject	Risk-Based Response to Shellfish-Related Illnesses Associated with Campylobacter spp.
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 (new paragraph J); new @.08 Shellfish-Related Illnesses Associated with Campylobacter spp.
11. Text of Proposal/ Requested Action	This proposal adds a new Model Ordinance section, Chapter II @.08, that sets out a risk-based, tiered response to shellfish-associated Campylobacter illnesses, patterned on the existing Chapter II @.02 for Vibrio parahaemolyticus. The new section (1) accounts for the time between harvest, illness onset, and case reporting; (2) distinguishes sporadic cases from clusters and outbreaks, using genetic relatedness where available; (3) uses risk per serving together with case counts so that a single sporadic case does not by itself trigger closure of a small production area; and (4) sets closure durations, reopening criteria, and harvest controls based on available purge and survival data. A conforming amendment to Chapter II @.01 routes these illnesses to the new section. New language is shown in red double underline. Deleted language is shown in blue strikethrough. The Executive Office is requested to adjust section and paragraph numbering as needed, including if the companion Salmonella proposal is also adopted. **1. Amend Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness, by adding a new paragraph J:** J. When the investigation outlined in Chapter II @.01 A. indicates that the illness(es) are associated with Campylobacter spp., the Authority shall follow the requirements of Chapter II @.08 in lieu of Chapter II @.01 B. through G., except as referenced in Chapter II @.08. **2. Add the following new section to Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management:** @.08 Shellfish-Related Illnesses Associated with Campylobacter spp. A. Applicability and Definitions. (1) This section applies when the investigation outlined in Chapter II @.01 A. indicates that the illness(es) are associated with thermotolerant Campylobacter spp. (Campylobacter jejuni, Campylobacter coli, or

Campylobacter lari) and the consumption of molluscan shellfish.

(2) For the purposes of this section:

(a) Case means a laboratory-confirmed Campylobacter infection, identified by culture or by a culture-independent diagnostic test (CIDT), that the state or local epidemiologist has determined is epidemiologically associated with the consumption of shellfish from the implicated area. In making this determination the epidemiologist should consider whether the interval between shellfish consumption and illness onset is consistent with the incubation period (typically two (2) to five (5) days) and whether other exposures documented in the food and exposure history (e.g., poultry, unpasteurized dairy products, untreated water, animal contact, or travel) provide a more likely source of infection.

(b) Sporadic cases means cases from an implicated area in which no two (2) cases are associated with a single harvest date and clinical isolates, where characterized, are not genetically related.

(c) Genetically related means that clinical isolates (and shellfish or environmental isolates, where available) have been determined to be closely related by whole genome sequencing (WGS) or another subtyping method used by PulseNet, as determined by the state public health laboratory or the Centers for Disease Control and Prevention (CDC).

(d) Harvest date means the date of harvest shown on the shellstock tag or, where tags are unavailable, the harvest date determined through traceback.

(e) Implicated area means the growing area, portion of a growing area, or aquaculture site from which the shellfish associated with the case(s) were harvested.

(f) Contributing condition means an identified or suspected source of Campylobacter contamination of the implicated area that the investigation associates with the case(s) or that exceeds conditions normally present in the growing area, including but not limited to congregations of birds and/or mammals on or around aquaculture gear or other structures, failing on-site sewage disposal systems, wastewater discharges, livestock, or agricultural runoff. The presence of birds or other wildlife at levels normally found in the growing area is not by itself a contributing condition.

(g) Risk per serving means the number of cases associated with shellfish harvested from the implicated area within a thirty (30) day period, divided by the number of servings harvested from the implicated area during the same period, expressed as illnesses per 100,000 servings. For this calculation one (1) serving equals twelve (12) oysters or hard clams, or the equivalent shucked meat weight, unless the Authority documents an alternative conversion consistent with that used for Vibrio risk-per-serving calculations.

B. Time Between Harvest and Case Reporting.

(1) Cases shall be attributed to the thirty (30) day period in which the implicated shellfish were harvested, regardless of the date the cases are reported to the Authority.

(2) States will not be expected to close growing areas based on cases reported more than thirty (30) days after the last implicated harvest date, unless the investigation in C. indicates that a contributing condition present at the time of harvest persists. When closure is not required under this subsection, the Authority shall complete the investigation in C., require correction of any contributing condition identified, and document its findings.

C. Investigation.

(1) Within seventy-two (72) hours of notification of a case, the Authority shall initiate an investigation to determine:

(a) The extent of the implicated area and the harvest date(s) of the implicated shellfish;

(b) Whether the illness(es) are growing area related or are the result of post-harvest contamination or mishandling, including cross-contamination during storage, preparation, or service (e.g., contact with raw poultry), or illegal harvesting from a closed area;

(c) Whether a contributing condition exists, including a review of bird and/or mammal congregations on or near aquaculture gear and of compliance with any operational plan required under Chapter VI. .04;

(d) Whether the growing area is properly classified, including a review of current water quality data and the sanitary survey; and

(e) The volume of shellfish harvested from the implicated area during the relevant thirty (30) day period, for the purpose of calculating risk per serving.

(2) If the conditions in D. (2) or D. (3) are met and the investigation cannot be completed within seventy-two (72) hours, the Authority shall immediately place the implicated area in the precautionary closed status. Should the Authority later determine that the illnesses are related to post-harvest contamination or mishandling, the implicated area may be immediately reopened.

(3) When the investigation demonstrates that the illnesses are related to post-harvest contamination or mishandling, growing area closure is not required and the Authority shall follow the requirements of Chapter II @.01 D.

(4) When the investigation identifies a human sewage source or an improperly classified growing area, the Authority shall also follow the requirements of Chapter II @.01 G.

D. Risk Management Actions. When the investigation in C. does not indicate post-harvest contamination, mishandling, or illegal harvesting from a closed area, the actions taken by the Authority shall be based on the number of cases,

their relationship to one another, and the span of time, as follows:

(1) Sporadic Cases. When a single case occurs within a thirty (30) day period from the implicated area, or when two (2) or three (3) sporadic cases occur within a thirty (30) day period and the risk does not exceed one (1) illness per 100,000 servings, the Authority shall:

(a) Determine the extent of the implicated area;

(b) Evaluate the implicated area for contributing conditions and, when a contributing condition is identified, require corrective action, which may include development or revision of an operational plan and mitigation or deterrent measures for birds and/or mammals under Chapter VI. .04;

(c) Notify the FDA Shellfish Specialist and the Authorities in receiving States of the case(s) and the actions taken; and

(d) Coordinate with the state epidemiologist to enhance surveillance for additional cases associated with the implicated area.

Closure of the implicated area is not required under this subsection.

(2) Clusters. When (i) two (2) or three (3) cases are associated with a single harvest date; (ii) two (2) or more cases are genetically related; (iii) two (2) or three (3) sporadic cases occur within a thirty (30) day period and the risk exceeds one (1) illness per 100,000 servings; or (iv) four (4) to six (6) cases occur within a thirty (30) day period from the implicated area, the Authority shall:

(a) Determine the extent of the implicated area;

(b) Immediately place the implicated area in the closed status. The closure may be limited to the implicated aquaculture site(s) and/or shellfish species when the investigation identifies a site-specific contributing condition;

(c) As soon as determined by the Authority, transmit to the ISSC, the FDA, and receiving States information identifying the dealers shipping the implicated shellfish;

(d) Determine the appropriateness of a voluntary recall by firms consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. A recall is not required when the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses; and

(e) Require correction of any contributing condition identified.

(3) Outbreaks. When four (4) or more cases are associated with a single harvest date, or more than six (6) cases occur within a thirty (30) day period from the implicated area, the Authority shall:

(a) Take the actions in D. (2) (a) through (c) and (e);

(b) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, unless the Authority determines that the implicated product is no longer available on the

market or that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products; and

(c) Issue a consumer advisory for the shellfish species implicated in the illnesses.

(4) The ISSC will notify States and FDA Shellfish Specialists of closures and recalls under D. (2) and D. (3), consistent with Chapter II @.01 C. (1) (e).

E. Multiple Implicated Areas. When the investigation does not identify a single implicated area, the Authorities in the States with implicated areas shall evaluate whether the illness(es) should be attributed to one (1) or more of the areas. Evaluations may include but are not limited to:

(1) Contributing conditions in each area at the time of harvest, including bird and/or mammal observations recorded by operators, enforcement staff, or sampling staff;

(2) Comparison with other cases attributed to the areas;

(3) Genetic comparison of clinical, shellfish, and environmental isolates; and

(4) Volume and distribution information.

If the evaluation implicates a single area, the Authority shall take the actions in D. Precautionary closures of multiple implicated areas are not required under D. (1). For D. (2) and D. (3), Chapter II @.01 C. (2) and (3) shall apply.

F. Closure Duration and Reopening.

(1) An area closed under D. (2) shall remain closed for a minimum of seven (7) days, and an area closed under D. (3) for a minimum of fourteen (14) days, from the date the Authority verifies that the contributing condition has been corrected or no longer exists or, when no contributing condition is identified, from the date of closure. When water temperatures in the implicated area are below 10 °C (50 °F), at which shellfish feeding is greatly reduced, the Authority should consider extending the closure period.

(2) Prior to reopening an area closed under this section, the Authority shall:

(a) Verify that the contributing condition has been corrected or no longer exists, including, for aquaculture sites, that required mitigation or deterrent measures are in place and functioning;

(b) Verify that the growing area meets the microbiological standards for its classification under Chapter IV. @.02; and

(c) When determined appropriate by the Authority, collect shellstock samples representative of the implicated area and shellfish types and analyze them for C. jejuni, C. coli, and C. lari using a method acceptable to the Authority until a method is adopted under Chapter III. Isolates recovered shall be submitted for whole genome sequencing or another subtyping method for comparison with the clinical isolates.

	Because Campylobacter spp. may be present in shellfish from growing areas not associated with illness, detection alone shall not be the basis for continued closure. If the outbreak strain is detected, the Authority shall continue the closure and re-evaluate the contributing condition. (3) The Authority shall develop a written report summarizing the findings of the investigation and the actions taken. G. Harvest from Closed Areas and Reconditioning. (1) Shellfish harvesting may occur in an area closed under this section, and shellfish recalled under this section may be reconditioned, when the Authority implements one (1) or more of the following controls: (a) Relaying the shellstock under Chapter V., or placing it in an approved or conditionally approved growing area in the open status where the contributing condition is absent, for not less than seven (7) days, with appropriate controls and documentation determined by the Authority; (b) Depuration in a certified depuration facility using a process the Authority determines, based on appropriate scientific studies, reduces Campylobacter to levels not reasonably likely to cause illness; (c) Post-harvest processing (PHP) using a process validated to reduce Campylobacter to levels not reasonably likely to cause illness; or (d) Other control measures that, based on appropriate scientific studies, are designed to ensure that the risk of Campylobacter illness is no longer reasonably likely to occur, as approved by the Authority.
12. Public Health Significance	**Campylobacter is a common foodborne pathogen but a rare shellfish hazard.** CDC estimates about 1.5 million Campylobacter infections in the United States each year, most of them linked to poultry, unpasteurized dairy, and produce. From 2000 to 2024, CDC outbreak surveillance recorded 11 Campylobacter outbreaks (66 illnesses) linked to oysters, compared with 190 Vibrio and 143 norovirus outbreaks linked to oysters over the same period (ISSC Aquatic Bird Risk Assessment Committee, draft final report). Source attribution using U.S. surveillance isolates attributes only about 3% of human campylobacteriosis to wild birds, compared with about 68% to poultry and 28% to cattle (Pascoe et al. 2024). Most Campylobacter strains, including many carried by birds, are not associated with human illness, and C. jejuni accounts for most human cases. **Background presence in growing areas.** Campylobacter spp. are commonly carried by gulls, waterfowl, and other wildlife and occur in estuarine waters and shellfish from growing areas that are not linked to illness (Carter et al. 1987). Much of what is found in these settings is C. lari or bird-adapted strains that are rarely associated with human illness (Smith et al. 2020). Detection in shellfish or water therefore does not by itself show that a growing area caused a case, and non-detection does not show that an area is free of risk. For this reason the proposal bases actions on case patterns, genetic relatedness, and risk per serving, and ties reopening to correcting the contributing condition rather than to non-detection. **Recent shellfish-associated events and a gap in the Model Ordinance.** Shellfish-associated Campylobacter outbreaks have been linked to birds congregating on

	floating aquaculture gear, including an October 2021 Rhode Island outbreak of C. jejuni (eight ill) (Caron et al. 2023; NSSP Guide Section IV, Chapter VI). In August 2025, Massachusetts closed Katama Bay (Edgartown) to oyster harvest after five confirmed Campylobacter illnesses linked to oysters harvested July 7–17 and eaten July 12–21. The closure took effect August 1, 15 days after the last implicated harvest date, and was to remain in place "until examined by the Division." The Model Ordinance currently addresses these illnesses only through the general outbreak provisions of Chapter II @.01. Under @.01, two illnesses in different households count as an outbreak and require immediate closure and consideration of recall. However, @.01 provides no guidance on sporadic cases, on the lag between harvest and case reporting, on risk relative to production volume, or on closure duration and reopening criteria suited to a bacterial pathogen that shellfish purge quickly. The result can be inconsistent responses between States and open-ended closures of small aquaculture operations. **Time from illness to reporting.** Campylobacter incubation is typically 2–5 days (CDC). For enteric bacterial pathogens, the time from exposure to confirmation that a case is part of an outbreak is typically 2–4 weeks, reflecting care-seeking, laboratory testing, isolate shipping, and subtyping (CDC, Timeline for Reporting Cases of Salmonella Infection). By the time a shellfish Authority is notified, the implicated lots may be beyond their market life, and a short-lived contamination event (e.g., a seasonal bird congregation) may have ended. The 30-day reporting window in the proposed @.08 B. matches the one in @.02 for V.p. It keeps closure authority when a contributing condition persists and still requires investigation and correction in every case. **Sporadic cases vs. outbreaks, and risk per serving.** Because Campylobacter is a common infection with many non-shellfish sources, a single reported case with a history of shellfish consumption does not show that the growing area is the source. The proposal therefore requires investigation and correction of contributing conditions for sporadic cases, and reserves closure for (i) multiple cases from a single harvest date, (ii) genetically related cases, (iii) sporadic cases that exceed the risk-per-serving benchmark already used in @.02 (one illness per 100,000 servings), or (iv) larger case counts. To keep a single case from triggering closure at low-volume sites, the risk-per-serving trigger applies only when two or more cases occur. WGS through PulseNet is now routine and lets investigators tell linked from unrelated cases. **Closure duration and reopening.** Preliminary results from an ISSC-funded study found that Eastern oysters exposed to C. jejuni, C. coli, and C. lari cleared all three species to below molecular (ddPCR) detection in tissue within two days (Richards, Noble and Smith, in prep.). A two-day depuration period was also effective for Sydney rock oysters (Arumugaswamy et al. 1988). Campylobacter can, however, survive in harvested shellfish for up to 22 days at 4 °C (Abeyta et al. 1993; Arumugaswamy et al. 1988), so recall stays relevant when product is still in commerce. The proposed minimum closures (7 and 14 days after the contributing condition is corrected) give a wide margin over observed purge times. The added caution at water temperatures below 10 °C reflects reduced oyster feeding. Fecal indicator bacteria correlate poorly with Campylobacter (Carter et al. 1987; Hellein et al. 2011; Caron et al. 2023). For that reason, reopening is tied to verified correction of the contributing condition, along with the classification standards.

	Optional shellstock testing is used to check whether the outbreak strain persists, not to require non-detection, because these organisms can be present in areas not associated with illness. **Consistency with ISSC work.** The proposal follows the direction of the Aquatic Bird Risk Assessment Committee, which recommends species-specific, risk-based management of C. jejuni, C. coli, C. lari, and Salmonella enterica rather than genus-level responses. It also follows the Committee's recommendation that shellfish Authorities work with epidemiologists to weigh other exposures when attributing illness to shellfish. It builds on the existing requirements for aquaculture sites that attract birds or mammals (Chapter VI. .04) and gives a proportionate, consistent response while research continues. **Supporting References** 1. Abeyta, C., et al. 1993. Campylobacter jejuni in a Washington state shellfish growing bed associated with illness. J Food Prot. 56:323-325. 2. Arumugaswamy, R., R. Proudford, and M. Eyles. 1988. The response of Campylobacter jejuni and Campylobacter coli in the Sydney Rock Oyster during depuration and storage. Int J Food Microbiol. 7:173-183. 3. Caron, G., et al. 2023. Campylobacter jejuni outbreak linked to raw oysters in Rhode Island, 2021. J Food Prot. 86:1-7. 4. Carter, A. M., et al. 1987. Seasonal occurrence of Campylobacter spp. in surface waters and their correlation with standard indicator bacteria. Appl Environ Microbiol. 53:523-526. 5. CDC. Clinical Overview of Campylobacter. https://www.cdc.gov/campylobacter/hcp/clinical-overview/index.html 6. CDC. Timeline for Reporting Cases of Salmonella Infection. https://stacks.cdc.gov/view/cdc/22424 7. CDC. BEAM (Bacteria, Enterics, Ameba, and Mycotics) Dashboard / NORS, 2000–2024, as summarized in the ISSC Aquatic Bird Risk Assessment Committee draft final report. 8. Hellein, K. N., et al. 2011. Culture-based indicators of fecal contamination and molecular microbial indicators rarely correlate with Campylobacter spp. in recreational waters. J Water Health. 9:695-707. 9. ISSC Aquatic Bird Risk Assessment Committee. Final Report: Aquatic Bird Risk Assessment Committee Literature Review (draft). 10. Massachusetts Division of Marine Fisheries. August 1, 2025. Oysters closure due to Campylobacter sp. outbreak in Edgartown (V20). https://www.mass.gov/doc/8125-oysters-closure-due-to-campylobacter-sp-outbreak-in-edgartown-v20/download 11. NSSP Guide for the Control of Molluscan Shellfish, 2023 Revision. Section II, Chapter II @.01–@.02; Section IV, Chapter VI. 12. Pascoe, B., et al. 2024. Machine learning to attribute the source of Campylobacter infections in the United States: A retrospective analysis of national surveillance data. J Infect. 89:1-10.

	13. Richards, G. P., R. Noble, and Smith. In prep. Campylobacter purge rates in Eastern oysters (Appendix 1, ISSC Aquatic Bird Risk Assessment Committee draft report). 14. Smith, O. M., W. E. Snyder, and J. P. Owen. 2020. Are we overestimating risk of enteric pathogen spillover from wild birds to humans? Biol Rev. 95:652-679.
13. Cost Information	No significant new costs are expected. WGS of clinical isolates is already performed routinely through PulseNet. Investigation requirements are similar to those already carried out under Chapter II @.01. Shellstock testing for reopening is optional and at the Authority's discretion. The proposal is expected to reduce economic losses to growers, especially small aquaculture operations, by avoiding closures and recalls that do not reduce risk, while keeping protective actions for clusters and outbreaks.
14. Changes Needed to Guidance (if proposed change is adopted)	No changes to the Guidance Documents (Section IV) are required for adoption. If adopted, the Executive Office is requested to make conforming cross-reference updates to Section IV guidance that refers to Chapter II @.01 outbreak response and to Chapter VI aquaculture bird and mammal requirements, so that it also references new Chapter II @.08.