Proposal No. 19-104

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Centers for Disease Control and Prevention (CDC)
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10. Proposal Subject	*Vibrio vulnificus* risk evaluation
11. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan Section III. Public Health Reasons and Explanations Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey ISSC Constitution, Bylaws & Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures
12. Text of Proposal/ Requested Action	**Section II. Model Ordinance Chapter II. Risk Assessment and Risk Management @.06 *Vibrio vulnificus* Control Plan** C. All States not currently implementing a *V.v.* Control Plan shall develop and implement a *V.v.* Control Plan ~~should~~ if the risk evaluation indicates two (2) or more etiologically confirmed, and epidemiologically linked *V.v.* ~~septicemia~~ illnesses from ~~the~~ consumption of commercially harvested ~~raw or undercooked~~ oysters that originated from the growing waters of that State within the previous ten (10) years **Section III. Public Health Reasons and Explanations Chapter IV. Shellstock Growing Areas @.01 Sanitary Survey** **A.** General. One of the goals of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times. Shellfish-borne infectious diseases are generally transmitted via a fecal-oral route. The pathway can become quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via runoff. Most freshwater streams eventually empty into an estuary where fecal bacteria and viruses may accumulate in sediment and subsequently can be re-suspended. Shellfish pump large quantities of water through their bodies during the normal feeding process. During this process the shellfish also concentrate microorganisms, which may include pathogenic microorganisms. Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct numerical correlation between the

bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the States and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than fifty (50) percent of the one (1) cc portions of water examined were positive for coliforms (an MPN of approximately seventy [70] per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States, the NSSP was initiated by the States, the Public Health Service, and the shellfish industry. Water quality criteria were then stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli- aerogenes group of bacteria in one (1) cc dilution of the growing area water. Once the standards were adopted in the United States in 1925, reliance on this three-part standard for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Similar water quality criteria have been used in other countries with favorable results.

Nevertheless, some indicators and pathogens are capable of persisting in terrestrial soil, fresh and marine waters, and aquatic sediment for many days while others are even capable of growth external to a host. A small number of shellfish-borne illnesses have also been associated with bacteria of the genus Vibrio. The *Vibrio spp.* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters.
Among the marine *Vibrio spp.* classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus*. All three (3) species have been recovered from coastal waters in the United States and other parts of the world. These and other *Vibrio spp.* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform.

In general, shellfish-borne Vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and *Vibrio* spp. counts were higher. *V. parahaemolyticus* and non~~-01~~O1 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish. In contrast, *V. vulnificus* has been related to~~ two (2) distinct syndromes:~~ wound infections, invasive disease usually characterized by bacteremia, and less commonly diarrheal illness associated with the consumption of seafood. ~~often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy. Increasing e~~Evidence shows that individuals with such chronic diseases such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy are susceptible to ~~septicemia~~ severe illness and death from raw seafood, especially raw oysters. Shellfish-borne Vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and

eating them promptly or storing them at hot (60 °C or higher) or cold (4 °C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to Vibrio infection during months when seawater is cold than when it is warm.

In addition to pathogenic microorganisms, poisonous or deleterious substances may enter shellfish growing areas via industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land or geochemical reactions. The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

The primary responsibility of the Authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area to one (1) of five (5) classifications. The survey information must be updated periodically to ensure that it remains current and must be readily accessible to both the Authority and the harvester. Experience has shown that the minimum sanitary survey components required in this chapter are necessary for a reliable sanitary survey. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2017).

ISSC Constitution, Bylaws & Procedures Procedure XVI. Procedure for *Vibrio vulnificus (V.v.)* Illness Review Committee Procedures

Section 1. Committee Charge

The *V.v.* Illness Review Committee will annually review all *V.v.* cases involving the consumption of shellfish which are reported to FDA regional specialists and the Center for Disease Control (CDC). The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V.v.* case as outlined in Model Ordinance Section II. Chapter II. @.05. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:

Subdivision a. Conducting annual *V.v.* Risk Evaluations;
Subdivision b. Risk per serving determinations;
Subdivision c. *V.v.* Control Plan Evaluations;
Subdivision d. *V.v.* Contingency Plan Evaluations; and
Subdivision e. Reviewing illness trends.

Section 2. Procedures.

Subdivision a. The Committee will only consider cases that are

reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other means.

Subdivision b. FDA will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the Committee.

Subdivision c. The information from the COVIS forms will be shared with the *V.v.* Illness Review Committee for review.

Subdivision d. The *V.v.* Illness Review Committee will review the cases and incorporate the appropriate information into a chart which will serve as the Committee report.

Subdivision e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.

Subdivision f. The availability of the report will be announced to the ISSC membership.

A copy of the report will be posted on the ISSC website.

Section 3. Criteria and Guidelines.

The Committee will use the following criteria and guidelines in reviewing reported cases:

Subdivision a. Was the illness etiologically confirmed? In this context "etiologically confirmed "shall mean laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory otherthan a State laboratory."

Subdivision b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

Subdivision c. Were the shellfish consumed?

Subdivision d~~e~~. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

~~Subdivision d.~~ ~~Were the shellfish raw or undercooked? If the victim developed *V.v.* septicemia after consumption the shellfish are considered to have been raw or undercooked.~~

Subdivision e. From what State was the shellfish harvested?

Subdivision f. ~~Did the case involve septicemia from consumption:~~

~~The following guidance will be used in~~

		~~determining if the case is a septicemia or a gastroenteritis case. Clinical signs and symptoms *V.v.* septicemia include:~~ A case of severe *V.v.* is defined as illness in a person who had V. vulnificus infection confirmed by bacterial culture and either of the following:	
		Subdivision i.	*V. vulnificus* was isolated from blood or a site that likely indicates invasive disease (see specimen source table).~~*V.v.* bacteria isolated from blood~~.
		Subdivision ii.	Any of the following were indicated on the COVIS case report form: 1. Fever 2. Septic Shock 3. Death Any of the following sequelae: necrosis; or invasive procedure, such as surgery, amputation, skin graft, wound debridement, fasciotomy, or incision and drainage~~Fever measured as above 100 degree Fahrenheit~~.
		~~Subdivision iii.~~	~~Death as outcome (septicemia has a mortality rate of over 50% – 70%).~~
		~~Subdivision iv.~~	~~Bullae (blood filled blisters) but this also can occur after a wound infection which becomes septic.~~
		~~Subdivision v.~~	~~Shock because of the sepsis (again this can happen also because of a wound infection).~~
	~~Subdivision g.~~	~~Indications case may not be *V.v.* septicemia from consumption:~~	
		~~Subdivision i.~~	~~Bacteria are only isolated from wound fluid or stool and no clinical evidence of septicemia.~~
		~~Subdivision ii.~~	~~Cellulitis. Since cellulitis is a localized or diffuse inflammation of connective tissue with severe inflammation of dermal and subcutaneous layers of the skin (bacteria entering~~

~~bodies through the skin, there might be a visible wound or just a small scratch), therefore more likely a wound infection.~~

~~Subdivision iii.~~ ~~History of pre-existing and sustained wound infection (If both wound and oyster/seafood consumption is documented and happened within the incubation period, there is no way to differentiate why the patient is septic.)~~

~~Subdivision iv.~~ ~~Septicemia has a much shorter incubation period compared to gastroenteritis, according to CDC data. *V.v.* septicemia has an incubation period between 12-72 hours, although we have seen cases with shorter incubation periods.~~

Section 4. Challenges to Committee Findings.

Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

Section 5. *V.v.* Case Appeal Procedure

Subdivision a. Appropriate V.v. information will be provided to the reporting and source States at least 60 days prior to committee review. The States will be given 30 days from the date of receipt to respond.

Subdivision b. Following V.v. Illness Review Committee review, each source State with a countable case will be notified.

Subdivision c. Should a source State disagree with the Committee determination on a specific case, the source State will be provided thirty (30) days to file an appeal.

Subdivision d. Should the Committee, based on the information provided by the appellant, conclude that the original determination should be reversed, the appellant will be notified.

Subdivision e. Should the Committee, based on the information provided by the appellant, conclude that the original determination was appropriate; the Committee will provide the appellant an

opportunity to state their position. This opportunity will be either by telephone conference call or in person. The choice of venue will be determined by the Committee and will not exceed fifteen (15) minutes.

Subdivision f. The Committee will consider information presented by the appellant in the oral presentation. The appellant will be notified of the final decision of the Committee.

Subdivision g. The appellant will receive a final decision from the Committee no more than 30 days after the date the appeal is submitted; if a decision can NOT be made after 30 days, then an appeal extension must be granted by the committee, or the appeal will be considered denied.

Table: Specimen sources that likely reflect invasive disease

Blood: Includes plasma and blood components
Vascular: Includes heart, heart valves, aorta, blood vessels
Lymphatic: Includes lymph, lymph nodes, thymus
Spleen: Includes spleen, splenic abscesses
Bone: Includes bone, bone marrow
Placenta and products of conception: Includes fetus, cord blood
Nervous system Cerebrospinal fluid (CSF) Other nervous tissue; includes brain abscess
Pleural fluid
Peritoneal fluid
Joint: includes synovial/joint fluid
Hepatobiliary: Gallbladder, bile, liver (includes abscesses)
Pancreas: Includes pancreas, pancreatic cysts, and abscesses
Reproductive: Ovary, fallopian tube, uterus (includes cysts and abscesses in these sites), pelvic abscesses, amniotic fluid
Kidney: Includes renal and perinephric abscess

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	Criteria Status		
Criteria	Yes	No	Unknown
1. Etiologically Confirmed? ~~Blood Stool~~			
2. Epidemiologically Linked?			
3. ~~Septicemia~~ Severe Illness?			
4. Reporting State?			
5. Commercial Harvest?			

6. Were shellfish consumed?				
a. Specify shellfish consumed:		Oysters	Clams	Specify Other
b. Date of consumption: _____				
c. Is onset consistent with consumption of shellfish? Date of onset _____				
7. Trace-back Information				
a. Were shipping tags available? If other trace-back information reported, list:				
b. State of harvest, harvest area (s), and harvest date (list all reported).				

Harvest	Harvest	Harvest	Species	Comment

13. Public Health Significance	Septicemia is an outdated term no longer commonly used in medicine or public health. An alternative strategy of considering only "severe" cases to reflect the magnitude of risk from food is problematic, because 1) the severity of an illness may depend on factors other than the food, such as the patient's age, underlying health conditions, access to healthcare, bacterial load ingested, and appropriateness of medical treatment, and 2) data collection practices, state resources, and availability of data can vary by geography and over time. This makes the reporting of "severe" cases potentially inconsistent. Surveillance data on method of preparation can be limited and subjective. Any oyster that transmits illness can be considered insufficiently cooked; consumers may not realize they have eaten an undercooked food. Counting all etiologically confirmed cases associated with consumption of commercially harvested oysters is the most clear and consistent measure of *V. vulnificus* illness risk to the public.

14. Cost Information	NA