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	ll for Task Force Consideration SSC 2017 Biennial Meeting	 Growing Area Harvesting/Handling/Distribution Administrative
Submitter	US Food & Drug Administration (FD	
Affiliation	US Food & Drug Administration (FDA)	
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Proposal Subject	Vibrio Control Plans	
Specific NSSP	Section II. Model Ordinance	
Guide Reference	Chapter II. @ .05 Vibrio vulnificus C	ontrol Plan
Text of Proposal/		
Requested Action	 Chapter II. @ .06 Vibrio parahaemolyticus Control Plan @.05 Vibrio sublifieus-Control Plan (Effective January 1, 2012) A. Risk Evaluation Each shellfish producing State that is not currently implementing a Vibrio sublifieus (V.v.) control plan for purposes of controlling the risk of Vibrio sublifieus (V.v.) and/or Vibrio parahaemolyticus (V.p.) shall conduct a Vibrio sublifieus (V.v.) and/or Vibrio parahaemolyticus (V.p.) shall conduct a Vibrio sublifieus (V.v.) and/or Vibrio parahaemolyticus (V.p.) shall conduct a Vibrio sublifieus (V.v.) and/or Vibrio parahaemolyticus (V.p.) shall conduct a Vibrio sublifieus (V.v.) and/or Vibrio parahaemolyticus (V.p.) shall conduct a Vibrio sublifieus (V.v.) and/or Vibrio factors, including seasonal variations in the factors, in determining the risk evaluation annually. The evaluation shall-should consider factors, including seasonal variations in the factors, in determining the risk evaluation the State Authority may will at a minimum consider any number of factors, for examplethe following: (a) The number of Vibrio vulnificus and Vibrio parahaemolyticus cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and (b) Levels of Vibrio vulnificus and Vibrio parahaemolyticus in the growing waters and in shellfish, to the extent that such data exists; and (c) Levels of tith + and th+ Vibrio parahaemolyticus in the growing area to the extent that such data exists; and (d) The water temperatures in the growing area; and (e) The air temperatures in the growing area; and (f) Salinity in the growing area; and (g) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP. B. The State shall develop a Vibrio Contingency Plan should the risk evaluation indicate: (1) Any etiologically confirmed shellfish-borne Vibrio vulnificus or Vibrio parahaemolyticus. Jilness	
		tet the illness threshold <u>for Vibrio vulnificus</u> and/or

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<u>Vibrio parahaemolyticus</u> requiring a Vibrio vulnificus Control Plan will continue to maintain and implement a Vibrio vulnificus Control Plan.

CD. All States not currently implementing a *Vibrio* vulnificus-Control Plan shall develop and implement a *Vibrio* vulnificus-Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio* vulnificus 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.

E. All states not currently implementing a *Vibrio* Control Plan shall develop and implement a *Vibrio* Control Plan should the risk evaluation indicate that the State has a shellfish growing area that was the source of oysters or hard clams (*Mercenaria mercenaria*) that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years.

D. The State shall develop a Vibrio vulnificus Contingency Plan should the risk evaluation indicate:

(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.04 C.; and

(2) Information on Levels of *Vibrio vulnificus*, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;

E<u>F</u>. <u>*Vibrio*</u> Control Plan

(1) The *Vibrio vulnificus*-Control Plan shall include the following:

(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:

- (i) The water temperatures in the area; and
- (ii) The air temperatures in the area; and
- (iii) Salinity in the area; and

(iv) Harvesting techniques in the area; and

(v) Other factors which affect risk which can be used as a basis for reducing risk.

(**ba**) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* illness:

(i) Labeling oysters and/or hard clams, "For shucking by a certified dealer", when the Average Monthly Maximum W water Temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold 70°F.
(ii) Subjecting all oysters and/or hard clams intended for the raw, half-shell market to Authority approved post-harvest processing when the Average Monthly Maximum W water Temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold 70°F.
(iii) Cooling oysters and/or hard clams to 50°F within one hour of harvest when the water temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness the temperature associated with Vibrio illnesses that caused the Maximum of harvest when the water temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.

Reducing time of exposure to ambient air temperature prior to

delivery to the initial certified dealer based on modeling or
sampling, as determined by the Authority in consultation with
FDA. For the purpose of time to temperature control, time
begins once the first shellstock harvested is no longer
submerged. When this control measure is selected, State V.v.
plans will include controls when water temperature promotes
V.v. levels and risk of illness increases. The controls will
minimize risk to less than three (3) illnesses per 100,000
servings when Average Monthly Maximum Wwater
Ttemperature exceeds 80°F. Authority approved Best
Management Practices (BMPs) will be applied to minimize V.v.
growth to the extent possible when Average Monthly Maximum
Water temperature exceeds 70°F but is less than or equal to 80
^o F. BMPs will ensure that when the water temperature exceeds
70°F but is less than or equal to 75°F risk is minimized to less
than 1.75 illnesses per 100,000 servings and when water
temperature exceeds 75°F but is less than or equal 80 °F the risk
will not exceed 2.5 illnesses per 100,000 servings. These risks
per serving will be determined using the FDA developed Vibrio
vulnificus calculator.
(iv)-Prohibiting the harvest of ovsters and/or hard clams when
water temperature exceeds the temperature associated with
Vibrio illnesses that caused the State to meet the illness
threshold. The State Authority may implement alternative
controls that will reduce the risk to a level comparable to the
risk per serving identified above in @.05 E. (1) (b) (iii) when
water temperatures exceed 70°F.
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Plans the evaluation shall determine: a. Dot the risk evaluation indicate the need for a Contingency Plan? b. Does the plan include the regulatory steps to be implemented should the number of illnesses reach the illness threshold requiring implementation of a Vibrio Control Plan? (c) The results of the State and USFDA evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures. FG. Contingency Plan (1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a Vibrio+. Control Plan. (2) Contingency Plan Shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a Vibrio+. Control Plan. (2) Contingency Plan	(iii) For Authorities required to develop Vibrio Contingency
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	(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and

south): 81°F.
(c) However, development of a Plan is not necessary if the State
conducts a risk evaluation, as described in Section A. that determines
that it is not reasonably likely that Vibrio parahaemolyticus illness will
occur from the consumption of oysters harvested from those areas.
(i) In conducting the evaluation, the State shall evaluate the
(1) In conducting the evaluation, the State shall evaluate the
factors listed in Section A. for the area during periods when the
temperatures exceed those listed in this section;
(ii) In concluding that the risk is not reasonably likely to occur,
the State shall consider how the factors listed in Section A.
differ in the area being assessed from other areas in the state and
adjoining states that have been the source of shellfish that have
been epidemiologically linked to cases of Vibrio
parahaemolyticus illness; or
(3) If a State has a shellfish growing area that was the source of oysters <u>and/that</u>
were epidemiologically linked to an outbreak of Vibrio parahaemolyticus within
the prior first (5) means the State shall develop and implement a Vil.
the prior five (5) years, the State shall develop and implement a Vibrio
parahaemolyticus Control Plan for the area.
(4) For States required to implement Vibrio parahaemolyticus Control Plans, the
Plan shall include the administrative procedures and resources necessary to
accomplish the following:
(a) Establish one or more triggers for when control measures are needed.
These triggers shall be the temperatures in Section B. (2) where they
apply, or other triggers as determined by the risk evaluation.
(b) Implement one or more control measures to reduce the risk of Vibrio
<i>parahaemolyticus</i> illness at times when it is reasonably likely to occur.
The control measures may include:
(i) Post harvest processing using a process that has been
validated to achieve a two (2) log reduction in the levels of total
Vibrio parahaemolyticus for Gulf and Atlantic Coast oysters and
a three (3) log reduction for the Pacific Coast oysters;
(ii) Closing the area to oyster harvest;
(iii) Restricting oyster harvest to product that is labeled for
shucking by a certified dealer, or other means to allow the
borond to be addressed by further processing:
hazard to be addressed by further processing;
(iv) Limiting time from harvest to refrigeration to no more than
five (5) hours, or other times based on modeling or sampling, as
determined by the Authority in consultation with FDA;
(v) Limiting time from harvest to refrigeration such that the
levels of total Vibrio parahaemolyticus after the completion of
initial cooling to 60°F (internal temperature of the oysters) do
not exceed the average levels from the harvest water at time of
harvest by more than 0.75 logarithms, based on sampling or
madeling as appressed by the Arthanites
modeling, as approved by the Authority;
(vi) Other control-measures that based on appropriate scientific
studies are designed to ensure that the risk of V.p. illness is no
longer reasonably likely to occur, as approved by the Authority.
(c) Require the original dealer to cool oysters to an internal temperature
of 50°F (10°C) or below within ten (10) hours or less as determined by
the Authority after placement into refrigeration during periods when the
rick of Vibrio narahaamolyticus illnoos is reasonably likely to occur. The
risk of Vibrio parahaemolyticus illness is reasonably likely to occur. The
dealer's HACCP Plan shall include controls necessary to ensure,
document and verify that the internal temperature of oysters has reached

Out (UPC) or below within text (U) hours or leaves determined by the Authority of being placed into refiguration. Optices without proper HACCP - recends - demonstrating - compliance - with - drives - conting requirement shall be diverted to PHD or babeled " <i>Gravitation alwave</i> the Plan is online means to allow the hazard to be addressed by further processing. (d) Furthante the effectiveness of the Plan. (e) Molify the Control Plan when the valuation shown the Plan is metic-take, or when new information is available or new technology makes this prudent as determined by the Authority. (f) Optional cost benefit analysis of the Vibrio parahaemolyticus Control Plan. C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellhood harvested is no longer submerged. Public Health Significance While Vibrio parahaemolyticus and Vibrio valnificus Control plans (VPCP and VVCP) require ty primarily on time and temperature controls to reduce post-harvest vibrio growth, the controls implemented vary widely from state to state. States requiring V.v. controls generally must implement more restrictive harvest controls than states which only require V.p. control plans. Additionally, risk per serving standards associated with VVCP require ty priorative strong the increases the right over his same period. Post-harvest growth increases the right over his same period. Post-harvest growth increases the right of Vp.p. V., and likely other Vibrio spp. and shall be prevented by any reasonable means. Enforcement of current time and temperature controls is problematic as it is difficult to determine when the product was harvested. Immediate cooling would prevent any vibrio growth and maintain the vibrio levels at harvest providing enhanced public health protection relative to the current control plans. Immediate cooling would prevent any vibri		
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	 Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and; Ensure that the results of research efforts will be fully considered by the membership of the ISSC.
	temperature controls, the Executive Office shall request that states and industry submit to the VMC data and information relative to efforts in their respective state associated with time and temperature assessment and control activities. This work shall be conducted over the next one to two years and the science that is generated and compiled shall be used to compose an ISSC Proposal for consideration at the 2015 biennial meeting of the ISSC for controlling the post-harvest growth of Vibrios. The Executive Board shall be briefed at each of its semiannual meetings regarding all ongoing work associated with this effort.
	Additionally FDA requested that the remaining Vibrio Proposals be debated as submitted.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force II on Proposal 13-204.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-204.
Action by 2015 Vibrio Management Committee	Recommended no action on Proposal 13-204. Rationale: The final reports from the ISSC funded studies have not been finalized and submitted to the ISSC. The final reports, when available, will be shared with VMC. The VMC will make recommendations to Task Force II to address Proposal 13-204 at that time.
Action by 2015 Task Force II	Recommended deferring action on Proposal 13-204. Rationale: The final reports from the ISSC funded studies have not been finalized and submitted to the ISSC. The final reports, when available, will be shared with VMC. The VMC will make recommendations to Task Force II to address Proposal 13-204 at that time.
Action by 2015 General Assembly	Adopted recommendation of Task Force II on Proposal 13-204.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-204.