	<p>Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting</p>	<p>a. <input checked="" type="checkbox"/> Growing Area b. <input type="checkbox"/> Harvesting/Handling/Distribution c. <input type="checkbox"/> Administrative</p>
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Proposal Subject	Classification of Shellfish Growing Areas Adjacent to Waste Water Treatment Plants	
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II. Growing Areas .19 Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants	
Text of Proposal/ Requested Action	<p style="color: blue;"><u>19. Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants</u></p> <p style="color: blue;"><u>A. Introduction</u></p> <p style="color: blue;">The original National Shellfish Sanitation Program (NSSP) principles have proved effective in controlling bacterial illness associated with shellfish harvested from polluted waters. These principles, namely a robust sanitary survey, regular water and shellfish monitoring using bacterial indicators, controlled harvest times and labelling the origin of shell stock remain applicable as the primary preventative food safety control measures for growing areas.</p> <p style="color: blue;">However, there is now ample scientific evidence to show that the current bacterial indicators are inadequate to predict the risk of viral illness for the following reasons:</p> <ol style="list-style-type: none"> (1) Enteric viruses are resistant to treatment and disinfection processes in a Waste Water System Discharge (WWSD) and are frequently detected in the WWTP's final effluent under normal operating conditions (Baggi et al. 2001; Burkhardt et al. 2005; Pouillot et al. 2015). (2) Shellfish can bioaccumulate enteric viruses up to 100 fold from surrounding water (Seraichekas et al. 1968; Maalouf et al. 2011). (3) Certain enteric viruses are retained by molluscan shellfish to a greater extent and for longer than the indicator bacteria currently used to classify shellfish growing areas (Sobsey et al. 1987; Dore 	

& Lees 1995; Love et al. 2010). It has been well documented that enteric virus detection is not indexed by levels of conventional indicator bacteria.

For several decades now viral illnesses, in particular norovirus (NoV) and Hepatitis A (HAV), have been the most common food safety problem associated with bivalve molluscan shellfish (Woods 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012; Hall et al 2012). NoV genogroups I, II and IV and HAV are typically associated with ill individuals and transferred by the fecal oral route. Because WWTPs do not completely remove infectious enteric viruses emphasis should be placed on the importance of ensuring there is adequate dilution between a sewage source and a shellfish growing area.

In addition to the risk of enteric viruses WWTP effluents may also contain other chemicals and deleterious substances including pharmaceuticals, nanoparticles, and other contaminants of emerging concern. Establishment of a prohibitive area in proximity to WWTP discharges is an effective strategy to reduce the risk posed by both enteric viruses and other contaminants found in WWTP effluents. This guide provides information on the recommended dilution rates with respect to enteric viruses to ensure WWTP effluent does not cause a significant viral food safety risk within shellfish growing areas. The guide also considers the factors that should be used to assess a WWTP.

B.Delineation of the Prohibited Area around a Waste Water System Discharge (WWSD)

The NSSP Model Ordinance Section II, Chapter IV, @.03 (2) (b) and @.03 E(5) states that all growing areas which have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the shellfish growing area must have a prohibited classification established adjacent to the outfall taking account of the following factors:

- (1) The volume flow rate, location of discharge, performance of the Waste Water System Discharge (WWSD) and the microbiological quality of the effluent;
- (2) The decay rate of the contaminants of public health significance in the wastewater discharged;
- (3) The wastewater's dispersion and dilution and the time of waste transport to the area where shellstock may be harvested; and
- (4) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

C.Establishing the Size of Each Prohibited Area There are several important considerations for the shellfish authority to consider when establishing the size of each prohibited area:

~~(1) The area to ensure that there is adequate dilution when the WWTP is operating as normal. "Normal" means that the WWTP is operating fully within the plant's design specifications, including design flows; treatment stages; disinfection; as well as compliance with all permit conditions that relate to the WWTPs effectiveness in reducing enteric viruses in sewage.~~

~~Below is not an exhaustive list but serves as examples of situations that could occur and are critical for Shellfish Control Authorities (SCAs) on evaluating each WWTP when developing Conditional Area Management Plan (CAMP):~~

~~(a) Bypassing stage of treatment~~

~~A plant may be considered operating outside of normal operation if a treatment stage such as primary or secondary treatment is bypassed which may result in an increased load of solids in the disinfection step and reduce the effectiveness of disinfection. An additional example would be when a WWTP experiences a loss in disinfection and thus the ability to effectively treat the final effluent. SCAs should determine the significance of these types of events and make appropriate provisions in the CAMP.~~

~~(b) Operating outside design specifications/other types of failures or events~~

~~It is not uncommon for a WWTP to periodically experience mechanical failures of equipment that could alter the treatment of sewage. Additionally, a WWTP may also need to periodically perform routine maintenance to the various stages of treatment and may need to temporarily take a portion of a treatment stage off line for cleaning. Other unexpected maintenance may need to occur for example bio-fouling of filters or membranes used in treatment. SCAs should be informed by WWTP operators of these events to determine if any additional temporary action is needed if not addressed in the CAMP.~~

~~(c) Operating above design flow~~

~~Some WWTPs may operate above its design flow and not necessarily bypass any particular stage of treatment. During these events it is typical for WWTP operators to adjust the operation of the WWTP which may include reducing the treatment time in the aeration stage and/or solids separation/settling stage of treatment. Under some circumstances this could lead to a significant reduction in the effectiveness of disinfection. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be~~

made in the CAMP.

(d)WWTP permit violations

If a WWTP is exceeding the permitted bacterial indicator levels in the final effluent this indicates that effectiveness of the disinfection step has been reduced. Other measured parameters in the effluent (e.g. Total Suspended Solids (TSS), Biochemical Oxygen Demand (BOD)) may also indicate a reduction in treatment efficiency as occurred. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be made in the CAMP.

Situations where compliance with permit but risk to shellfish growing area:

There could be situations in which a particular WWTP could be in compliance with a permit, and could still pose a risk to the shellfish harvest area. For example, a WWTP may have permit conditions to allow for flow blending during high flow periods where a portion of the sewage may receive full treatment but a portion of the sewage may only be partially treated and “blended” in the final disinfection step. Although this may be an acceptable practice under a permit it could result in conditions in which the efficiency of the WWTP to remove enteric viruses is considerably reduced. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events and if additional provisions should be made in the CAMP.

(2) That the collection system has no malfunctions, bypasses or other factors that would lead to significant leakages of untreated sewage to the marine environment.

(3) That there is adequate detection and response time when any malfunction occurs to ensure that all harvesting ceases and closures are enforced, so that contaminated product does not reach the market.

Additional considerations

It is critical for SCAs to communicate with WWTP operators and ensure that there is no confusion over how SCAs define “outside of normal operation” in a Conditional Area Management Plan (CAMP) which may differ from how “malfunctions” or “violations” are defined in a permit. The SCAs also need to ensure that the WWTP operators understand the CAMP and that shellfish growing areas may close based on conditions of the CAMP even though the WWTP is operating in compliance within permitted conditions. Thus, it is important to communicate with WWTP operators to ensure that when shellfish closures occur and are reported that SCAs are using terminology that is understood by both parties.

D.Guidelines for Dilution, Dispersion, and Time of Travel of Effluent

Dilution refers to the dilution of effluent that occurs when the effluent is subjected to a number of physical processes in the receiving waters including turbulent mixing of the effluent in the vicinity of the outfall and at further distances primarily through tidal action, wind, and density stratification. Dispersion refers to the spread, location, and shape of the effluent discharge plume with time as it leaves the WWTP outfall. Time of travel refers to the time it takes effluent to reach the shellfish harvest site starting from the point of discharge.

It is essential to recognize that water samples collected near discharge outfalls are not useful for determining the size of prohibited areas because normal operating conditions in WWTPs can effectively reduce or even eliminate the fecal and total coliforms which are the current indicator microorganisms used to assess treatment efficiency. In contrast, many human enteric viruses are not inactivated by functioning WWTP treatment and disinfection systems, hence the need for an adequate dilution zone between the outfall and the shellfish resource.

It is important to consider not only the WWTP discharge, but also overflow points on the collection system such as those from pumping stations. While a malfunctioning WWTP may provide partial treatment, the discharge from a collection system is untreated and may be a more common failure point in the overall system.

When determining if a WWTP or collection system discharge within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, in the absence of a performance history of the treatment and collection system, and a database of influent and effluent quality, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance, if a level of 1.4×10^6 FC/100ml is assumed for a raw sewage release, a 100,000:1 dilution would be required to dilute the sewage sufficient to meet the approved area standard of 14 FC/100ml. If dilution analysis determines that the location of the discharge is such that the dilution of effluent would be greater than 100,000:1 then the WWTP could be considered located outside the zone of influence to the shellfish growing area. Different dilution ratios may be applied depending on the known concentration of sewage, provided that the water quality objective of the downstream harvest area is met.

In areas where the required WWTP discharge dilution is less than 100,000:1 and/or a raw sewage release results in FC levels in the growing area of >14 FC/100 ml a conditional management may be considered. However, conditional management is only recommended for, highly efficient WWTPs that are well monitored to detect malfunctions and changes in effluent quality and when the shellfish authority has the resources to effectively administrate and patrol the conditions of the growing area management plan.

In all cases the FDA recommends the minimum of a 1000:1 dilution around

~~a WWTP outfall to mitigate the impact of viruses on shellfish growing areas.~~

~~A dye study can be used to measure the dilution and dispersion of the effluent during specific discharge conditions. Computer modeling programs can also be used to estimate the dispersion and dilution of the effluent plume from WWTPs and collection system overflows.~~

~~E. Scientific Rationale for 1000:1 Dilution Guidance~~

~~In 1995 the FDA determined the 1000:1 dilution was necessary using the most relevant the scientific literature available at that time (Kohn, et al. 1995; Havelaar et al. 1993; Kapikian et al. 1990; Liu et al. 1966). In 2008 FDA performed an investigation in the upper portion of Mobile Bay, Alabama, the results of which were published in the Journal of Shellfish Research (Goblick, et al., 2011). The article describes how FDA used technical advances to assess the 1995 1000:1 dilution recommendation. The Mobile Bay study confirmed that this level of dilution was appropriate to mitigate the risk of viruses discharged in treated wastewater effluent.~~

~~Since the 2008 Mobile Bay study there have been major advances in the detection and enumeration of NoV in wastewater and shellfish and fluorometer technologies have enabled more sophisticated hydrographic dye study methods. Using these advances, FDA has now conducted numerous dye studies supplemented with the testing of shellfish sentinels for enteric viruses and their surrogates. The findings from these studies demonstrate that achieving a steady state 1000:1 dilution level in the requisite Prohibited area appears to be adequate for mitigating the impacts of viruses on shellfish when WWTPs have typical treatment and disinfection practices, such as secondary treatment and chlorination, and when operating under normal conditions.~~

~~While evaluating the 1000:1 dilution level Male Specific Coliphage (MSC) results in shellfish from the 2008-2015 studies were evaluated. These collaborative studies with State Shellfish Control Authorities and Industry were conducted in the Gulf, Mid Atlantic, East and West Coast, and under varying hydrographic and meteorological conditions. Various additional factors were considered such as type of wastewater treatment and disinfection technology, seasonal conditions, and shellfish species etc. and are represented in the data collected. In some cases, data was collected during a period of which the WWTP was considered to be operating outside of “normal” operating conditions. In other cases, the WWTP was considered not suitable for conditional area management due to design/poor performance even during routine/normal operation. Focus was given to the MSC threshold of 50 PFU/100 grams of shellfish tissue which is the level used for re-opening harvest areas after an emergency closure due to raw untreated sewage discharged from a large community sewage collection system or a WWTP (Model Ordinance (Section II, Chapter IV, @.03 A(5)(C)(ii))). From the 2008-2015 studies, a total 216 samples were assessed including conditions when the WWTPs were considered operating normally as well as under a bypass or degraded operation conditions. In summary, 216 samples were analyzed for MSC of which 176 samples (81%) were~~

positive for MSC; 118 samples (67%) contained MSC levels > than 50 PFU/100 grams; and 43 samples (20%) had MSC levels > 50 PFU/100 grams and wastewater effluent dilution was greater than 1000:1. These results are shown in Figure 1 and Table 1 below:

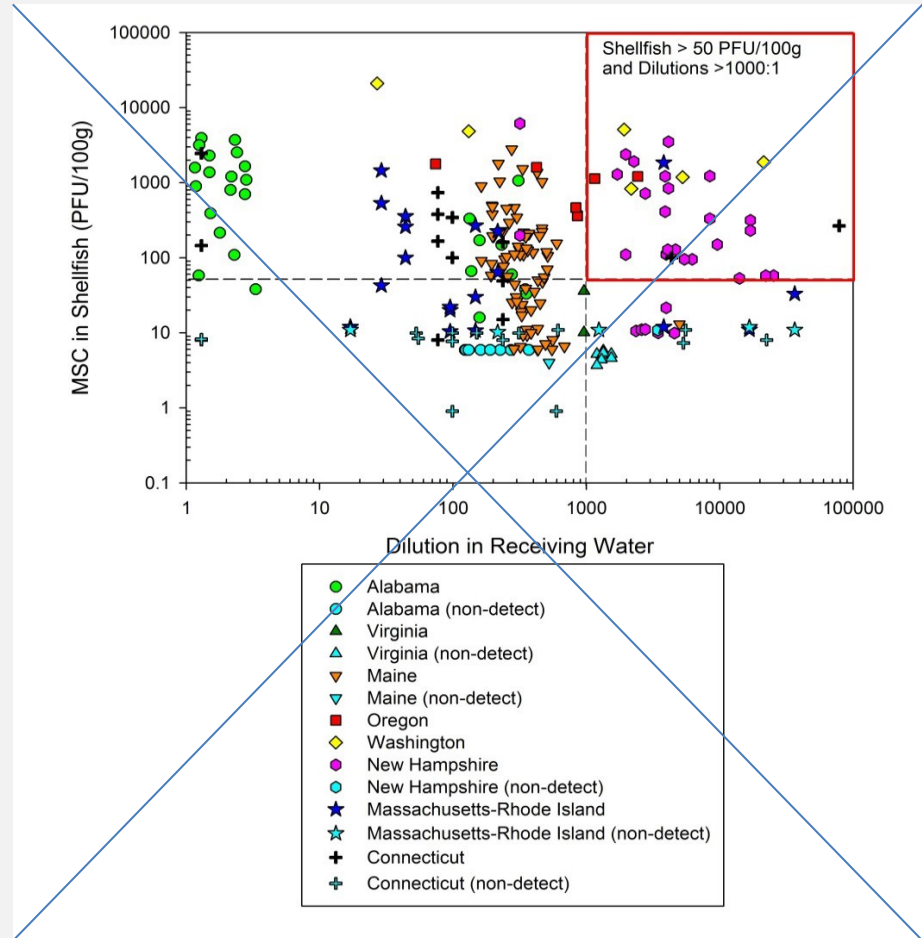


Figure 1: Comparison of dilution in receiving water and MSC levels in shellfish—all conditions Table 1: MSC in shellfish operating under “normal” and outside of normal operation

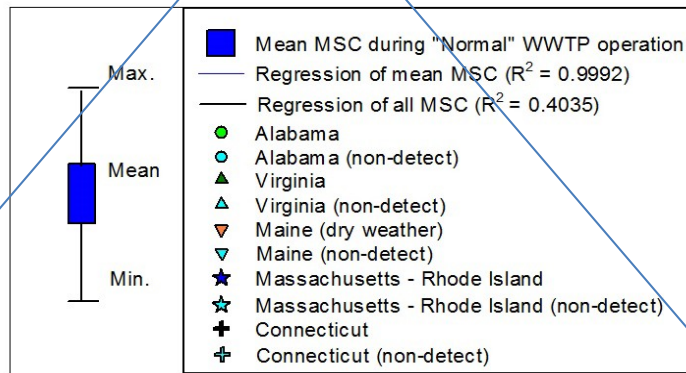
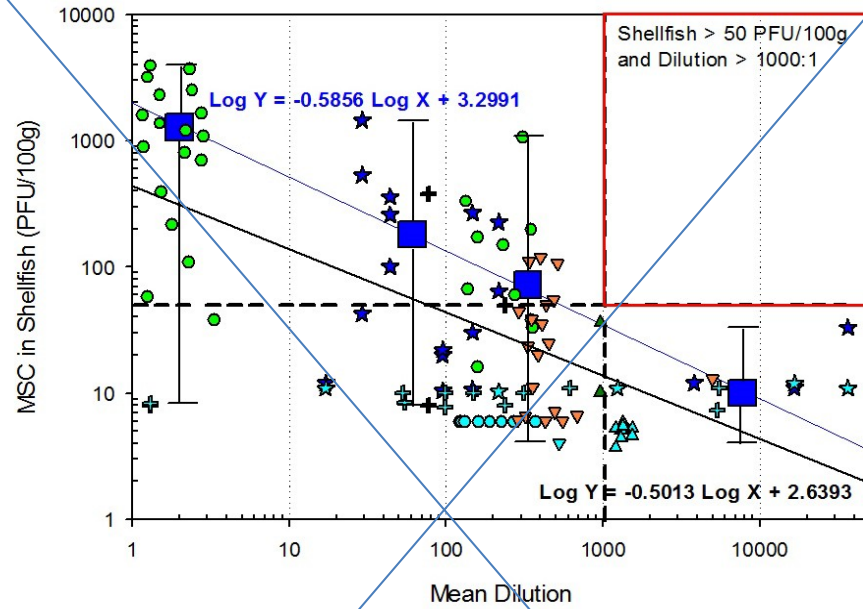
MSC Results	All Conditions (n=216)	Normal Operating Conditions (n=129)
MSC detectable	81% (176)	62% (80)
MSC levels >50 pfu/100g	67% (118)	36% (46)
MSC levels >50 pfu/100g and Dilution in Growing Area >1000:1	20% (43)	0% (0)

In separating the data attributed to “normal” operation from other conditions, 129 of the 216 total samples were considered to be attributed to

~~“normal” WWTP operation, also shown on Table 1. Eighty seven (87) samples were removed as they were attributed to conditions of WWTP malfunction or situations considered not suitable for conditional area management. From the 87 samples, 80 were associated with degraded WWTP performance or malfunction of which 6 were associated with a primary bypass, 13 were associated within a period of a WWTP upgrade during which the WWTP reportedly was operating an extended period (weeks) without disinfection, 31 were associated with degraded treatment quality because of rainfall/flows exceeding the WWTP design capacity, and 30 were attributed to a WWTP with no secondary treatment and operated frequently with flows exceeding the design capacity. Of the remaining 7 samples, 6 were associated with a WWTP utilizing unconventional disinfection technology (membrane filtration) and demonstrated poor performance in removing viruses compared to other conventional technologies during normal operating conditions, and 1 sample was attributed to a potential point source sewage discharge other than the WWTP.~~

~~When considering the remaining 129 samples attributed to “normal” WWTP operating conditions there were no samples that were above 50 PFU/100 grams when dilution was greater than 1000:1. In comparison, of the 87 samples attributed to malfunction or unsuitable conditions, 43 samples exceeded 50 PFU/100 grams when dilution was greater than 1000:1. These results are shown in Figure 2 below.~~

~~Figure 2: Comparison of dilution in receiving water and MSC levels in shellfish under normal operation~~



Comparing MSC with NoV sample results, out of the 216 samples analyzed for MSC, 161 samples were also analyzed for NoV. Of the 161 samples tested for NoV, 66 were positive (41% of total) were positive for NoV. Out of the 66 NoV positive samples, 62 (94% of total) were also positive for MSC and 53 (85% of total) had levels greater than 50 PFU/100 grams. There were only 4 cases where NoV was positive but MSC was not detected. However, in these cases, 3 of the sample results were near the Limit of Detection (LOD) for NoV enumeration. In one case it is suspected that both MSC and NoV may have been present but not likely viable as the WWTP utilized UV disinfection and was operating under normal conditions. These results are shown in Figure 3 and Table 2 below:

Figure 3: Comparison of MSC and NoV results

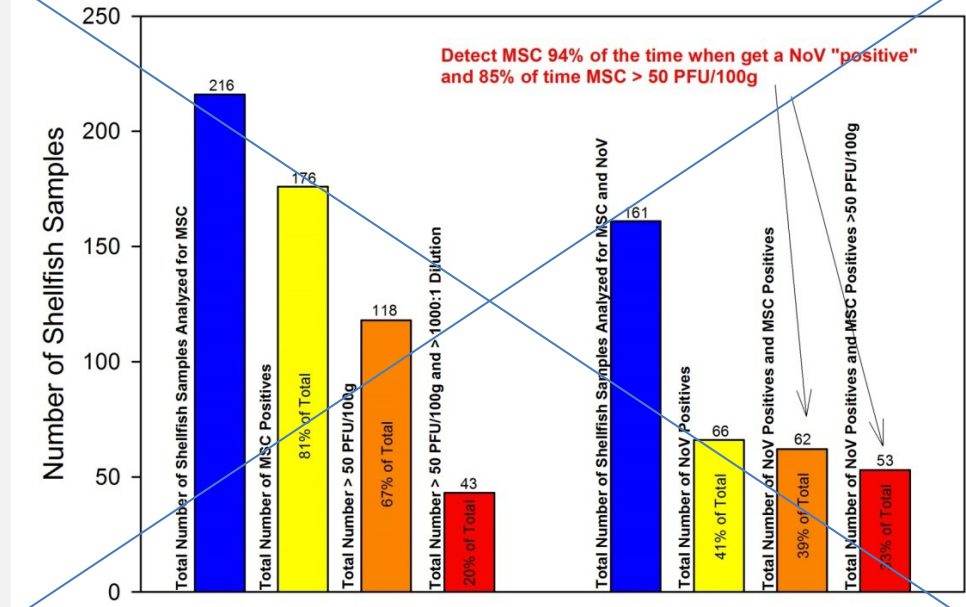


Table 2: Comparison of MSC and NoV Results in shellfish

MSC and NoV Results	
NoV detected in shellfish	41% (66 of 161)
MSC detectable	39% (62 of 161)
MSC negative when NoV detected (MSC<10 pfu/100g)	7% (4 of 66)*
MSC present when NoV detected (MSC>10 pfu/100g)	94% (62 of 66)
MSC present when NoV detected (MSC>50 pfu/100g)	85% (53 of 66)

*NoV detected at LOD of Assay

The overall results of FDA’s field studies demonstrate a strong relationship between increased levels of enteric viruses and MSC and decreased levels of dilution. This trend was observed in all of the studies conducted by FDA at conventional WWTPs. These results also emphasize the critical need for sufficient notification time, meaning travel time from the WWTP discharge in the prohibited area is long enough to close the shellfish growing area in the event of a malfunction. This preventative measure may necessitate the Prohibited Area be larger than the zone necessary to achieve 1000:1 dilution. Furthermore, this analysis demonstrates the need to individually assess each WWTP, to assess their performance to remove enteric viruses.

In addition to the FDA field studies, as part of a Joint United States-Canada Norovirus in Bivalve Molluscan Shellfish Risk Assessment, a Meta-Analysis of the Reduction of NoV and MSC Concentrations by

Wastewater Treatment was conducted (Pouillot, 2015). The meta-analysis included previously unpublished surveillance data from the United States and Canada and relevant data reported in the literature (2,943 measurements in total).

For WWTPs with mechanical systems and chlorine disinfection, mean log₁₀ reductions were 2.4 log₁₀ gc/liter, for NoV GI, 2.7 log₁₀ gc/liter, for NoV GII, and 2.9 log₁₀ PFU per liter for MSCs. Comparable values for

WWTPs with lagoon systems and chlorine disinfection were 1.4 log₁₀ gc/liter for NoV GI, 1.7 log₁₀ gc/liter for NoV GII, and 3.6 log₁₀ PFU per liter for MSCs. WWTPs with ultra violet (UV) disinfection demonstrated slightly higher mean log₁₀ reductions with 3.0 log₁₀ gc/liter, for NoV GI, 3.3 log₁₀ gc/liter, for NoV GII, and 4.3 log₁₀ PFU per liter for MSCs. The results of the reduction of NoV and MSC are shown in Table 3 below:

Table 3: Log reduction in NoV and MSC in treated wastewater with disinfection

Wastewater Treatment and Disinfection	Log₁₀ NoV GI Reduction	Log₁₀ NoV GII Reduction	Log₁₀ MSC Reduction
Mechanical with Chlorine Disinfection	2.4	2.7	2.9
Lagoon with Chlorine Disinfection	1.4	1.7	3.6
Mechanical with UV Disinfection	3.0	3.3	4.3

This meta-analysis also demonstrated that Chlorine Disinfection had little effect on the mean reductions of the NoV and MSC. The mean log₁₀ reduction that occur due to mechanical and biological treatment of the facility (prior to disinfection) were 2.2 log₁₀ gc/liter, for NoV GI, 2.5 log₁₀ gc/liter, for NoV GII, and 2.4 log₁₀ PFU per liter for MSCs which varied little from mean log reduction after disinfection. In addition, a strong correlation, 0.8, existed between the reductions of NoV GII and MSC that occurred following treatment at the same WWTP indicating that MSCs could be useful in evaluating the efficiency of a WWTP.

F. Alternate Options

The FDA studies also suggested that certain factors, such as the quality of sewage treatment or the time of year, may exert influences on the levels of viruses discharged. However, at this time FDA does not have reliable data to justify specific dilution levels associated with environmental variables. It is recognized that such criteria could be determined by SCAs on a case by case basis, where factors of WWTP performance, disinfection method, tidal flushing, shellfish species and seasonal impacts may vary.

For example, in consideration of a raw sewage discharge, a lower dilution level than a 100,000:1 could be justified provided that specific data to that particular WWTP demonstrates that a lower bacteriological level associated with a potential raw sewage discharge is supported. Additional or other site specific information also can be used to justify alternative approaches that take into account other factors (such as no prior history of raw sewage discharges or containment structures sufficiently sized to accommodate a raw sewage event preventing a discharge).

Alternative options for calculating the size of the prohibited area to mitigate the virological effects of WWTP discharges at the shellfish growing area may be used provided that they are based on sound scientific principles that can be verified. For example, it is reasonable to

expect a potentially higher reduction in viral load from a properly maintained wastewater treatment system employing ultraviolet (UV) disinfection, tertiary treatment and operating under optimum design flow conditions. Regardless of the technology employed any proposed alternative minimum level of dilution for conditional management other than 1000:1 would need validation. MSC could potentially be used on a case-by-case basis as the validation process (for example to validate treatment efficiency) if demonstrated it is a successful/feasible strategy for the given location/situation. However, when there is insufficient information available for a growing area to support the use of a lower level of dilution, the 1000:1 dilution should be employed. If MSC is selected as an alternative option for calculating the size of the prohibited area of a WWTP discharge, the authority should select an MSC criteria that adequately protects shellfish growing areas from virological effects and should be based on the most recent data and regional studies.

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Note: When the above document is removed from the NSSP Guide, it will be available on the ISSC website at www.issc.org/document-library.

.19 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants

Note: NSSP Model Ordinance excerpts are listed in italics.

I. Introduction

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.

The primary responsibility of the State Shellfish Control 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 growing areas one (1) of five (5) classifications.

The shoreline survey (also known as the pollution source survey) is the sanitary survey component in which the actual and potential pollution sources that may adversely affect the growing area are identified. These sources may introduce infectious disease agents or poisonous and deleterious substances to the growing waters where they may be taken up and concentrated by shellfish. Detailed and accurate information concerning the pollution sources is necessary for a proper growing area classification.

The key to the accurate classification of shellfish growing areas is the sanitary survey. The principal components of a sanitary survey include: (1) an evaluation of the pollution sources that may affect the areas; (2) an evaluation of the meteorological factors; (3) a review of hydrographic factors that may affect distribution of pollutants throughout the area; and (4) an assessment of water quality.

A pollution source survey must be conducted of the shoreline area and watershed to locate direct discharges (e.g., municipal and industrial waste discharges and package treatment units) and non-point sources of pollution (e.g., septic tanks, storm water runoff and agricultural and wildlife area runoff). Municipal and industrial wastewater treatment facilities should be evaluated in terms of design capacity versus actual loading, type and concentration of pollutants discharged, and the type and effectiveness of pollution control devices.

Water samples are collected to determine if the water quality meets the water quality standards for this growing area classification. The NSSP recognizes two (2) water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition monitoring

system to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the monitoring system used dictate the frequency of samples that must be collected for application of the water quality standards.

The original National Shellfish Sanitation Program (NSSP) principles have historically proved effective in controlling bacterial illness associated with shellfish harvested from polluted waters. These principles, namely a robust sanitary survey, regular water and shellfish monitoring using bacterial indicators, controlled harvest times and labelling the origin of shell stock remain applicable as the primary preventative food safety control measures for growing areas.

However, there is now ample scientific evidence to show that the current bacterial indicators are inadequate to predict the risk of viral illness for the following reasons:

- (1) Enteric viruses are resistant to treatment and disinfection processes in a Waste Water Treatment Plant (WWTP) and are frequently detected in the WWTP's final effluent under normal operating conditions (Baggi et al. 2001; Burkhardt et al. 2005, Pouillot et al. 2015).
- (2) Shellfish can bioaccumulate enteric viruses up to 100-fold from surrounding water (Seraichekas et al. 1968; Maalouf et al. 2011).
- (3) Certain enteric viruses are retained by molluscan shellfish to a greater extent and for longer than the indicator bacteria currently used to classify shellfish growing areas (Sobsey et al. 1987; Dore & Lees 1995; Love et al. 2010). It has been well documented that enteric virus detection is not indexed by levels of conventional indicator bacteria.

For several decades now viral illnesses, in particular norovirus (NoV) and hepatitis A (HAV), have been identified as common food safety problems associated with the consumption of bivalve molluscan shellfish (Woods 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012; Hall et al 2012). NoV genogroups I, II and IV and HAV are typically associated with ill-individuals and transferred by the fecal-oral route. Because WWTPs do not completely remove infectious enteric viruses emphasis should be placed on the importance of ensuring there is adequate dilution between a sewage source and a shellfish growing area.

In addition to the risk of enteric viruses present in wastewater, WWTP effluents may also contain chemicals and other deleterious substances including pharmaceuticals, nanoparticles, and other contaminants of emerging concern. Establishment of appropriate classification based upon virus removal efficacy and proximity and

source strength of WWTP discharges is an effective strategy to reduce the risk posed by both enteric viruses and other contaminants found in WWTP effluents. NSSP requires that shellfish growing waters be classified into one of five classifications. They include:

- (1) Prohibited – A classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.
- (2) Restricted – A classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.
- (3) Conditionally Restricted - A classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.
- (4) Conditionally Approved - A classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.
- (5) Approved - A classification used to identify a growing area where harvest for direct marketing is allowed.

This guidance document provides information on the five shellfish harvest classifications and the appropriate use of these classifications impacted by WWTP effluents. A sanitary survey report is required prior to the establishment of the classifications listed above with the exception of areas classified as prohibited.

II. General Requirements for Growing Area Classification

A. Chapter IV. Shellstock Growing Areas

@.01 Sanitary Survey

A. General.

- (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:
 - (a) A shoreline survey;
 - (b) A survey of the microbiological quality of the water. In growing areas adjacent to wastewater system discharges the State

Shellfish Control Authority may utilize MSC results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report;

(c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; and

(d) A determination of the appropriate growing area classification.

(2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with Section C. to assure that data is current and that conditions are unchanged.

(3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from:

(a) The sanitary survey;

(b) The triennial reevaluation; and

(c) The annual review.

(4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.

(5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.

B. Sanitary Survey Required.

(1) A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as prohibited.

(2) A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:

(a) The harvest of shellstock for human consumption; and

(b) The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.

C. Sanitary Survey Performance.

(1) A sanitary survey of each growing area shall be performed at least once every twelve (12) years and shall include the components in Section A. (1).

(2) When a written sanitary survey report is not

- completed, the area shall be placed in the closed status.
- (3) The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three (3) years.
- (a) This triennial reevaluation shall include:
- (i) A review in accordance with Section C. (5) and (6) of the water quality samples;
 - (ii) Documentation of any new pollution sources and an evaluation of their effect on the growing area;
 - (iii) Reevaluation of all pollution sources, including the sources previously identified in the sanitary survey, as necessary to fully evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;
 - (iv) A comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised; and
 - (v) If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.
- (b) When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.
- (4) The triennial reevaluation may include:
- (a) Inspection of waste water system discharges (WWSD) or collection of additional effluent samples to determine their impact on the growing area;
 - (b) Hydrodynamic studies;
 - (c) Additional field work to determine the actual impact of pollution sources; and
 - (d) Collection of additional water samples.
- (5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual

reevaluation shall include:

- (a) A field observation of the pollution sources which may include:
 - (i) A drive-through survey;
 - (ii) Observations made during sample collection; and
 - (iii) Information from other sources.
- (b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in Section @.02;
- (c) Review of available inspection reports and effluent samples collected from pollution sources;
- (d) Review of available performance standards for various types of discharges that impact the growing area; and
- (e) A brief report which documents the findings of the annual reevaluation.
- (f) The SSCA may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of waste water system discharge (WWSO) impacts on shellfish growing areas. If MSC meat and/or water data is being used, the SSCA shall conduct annual sample collection and analysis in determining performance standards.
- (6) If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

D. Shoreline Survey

Requirements.

- (1) In the shoreline survey for each growing area, the Authority shall:
 - (a) Identify and evaluate all actual and potential sources of pollution which may affect the growing area;
 - (b) Determine the distance from the

pollution sources to the growing area and the impact of each source on the growing area;

(c) Assess the reliability and effectiveness of sewage or other waste treatment systems;

(d) Determine if poisonous or deleterious substances adversely affect the growing area; and

(e) Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas.

(2) The Authority shall assure that the shoreline survey meets the following minimum requirements:

(a) The boundaries, based on the area topography, of each shoreline survey area are determined by an in-field investigation which identifies only the properties with the potential to impact the shellfish waters;

(b) Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;

(c) Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel; and

(d) Documentation for each pollution source identified by the Authority as affecting a growing area includes:

(i) The location of the site on a comprehensive map of the survey area; and

(ii) The determination that the pollution source has a direct or indirect impact on shellfish waters; and

(e) A written summary of the survey findings.

III. Guidance for Growing Area Classification

As a result of the information gathered during the sanitary survey, the Authority is responsible for distinguishing those growing areas suitable for harvest of shellstock for direct human consumption, those growing areas where the shellfish will require treatment prior to consumption, and those

growing areas unsuitable to harvest for human consumption. The probable presence or absence of pathogenic microorganisms, marine Biotoxin or other poisonous or deleterious substances in growing area waters is important to the Authority in deciding how the shellfish obtained from the growing area should be used. The Authority's decision, based on the sanitary survey information, will place all actual and potential growing areas in one of the five possible NSSP growing area classifications.

The five (5) growing area classifications are approved, conditionally approved, restricted, conditionally restricted and prohibited. Except for an emergency situation such as conditions following a hurricane when a growing area in the approved classification may be placed temporarily in the closed status, a growing area in the approved classification is always in the open status. The remaining four growing area classifications all place some type of restriction on shellstock harvesting. For more information concerning the enforcement of these restrictions, see the NSSP Guidance Document, Growing Area Patrol and Enforcement of Growing Area Restrictions (ISSC/FDA, 2015).

IV. Prohibited Classification

A. Definition

A classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.

B. Requirements for a Prohibited Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.

(1) Emergency Conditions...

(2) Classification of All Growing Areas. All growing areas which:

(a) Are not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited;

(b) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited

classification established adjacent to the outfall in accordance with Section E. Prohibited Classification; and

(c) Are subjected to...

(3) Boundaries...

(4) Revision of Classifications...

(5) Status of Growing Areas...

(2) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

E. Prohibited Classification.

(1) Exception...

(2) General...

(3) Sanitary Survey. A growing area shall be classified as prohibited if:

(a) No current sanitary survey exists;

(b) A sanitary survey determines:

(i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;

(ii) Pollution sources may unpredictably contaminate the growing area;

(iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors of disease microorganisms;

(iv) The concentration of...

(v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.

(4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II. Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.

(5) Wastewater Discharges.

(a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.

(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

(i) The volume flow rate, location of discharge, performance of the

wastewater treatment plant and the microbiological quality of the effluent. The SSCA may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;

(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;

(iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and

(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

C. Allowable Uses of Shellfish from a Prohibited Growing Area

(1) Depletion

Depletion means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.

(2) Seed

Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Depletion and Gathering of Seed

(1) Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

E. Prohibited Classification

(1) Exception...

(2) General. The Authority shall:

(a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed for aquaculture or the depletion of the areas classified as prohibited; and

(b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it is seed to be cultured as outlined in the NSSP Model Ordinance Chapter VI. Shellfish

- Aquaculture @.02 Seed Shellstock.*
- (3) Sanitary Survey...*
- (4) Risk Assessment...*
- (5) Wastewater Discharges...*

Chapter VI. Shellfish Aquaculture

Requirements for the Harvester/Dealer

.03 Seed Shellstock

Seed may come from any growing area, or from any growing area in any classification, provided that:

- A. The source of the seed is sanctioned by the Authority; and*
- B. Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of six (6) months.*

E. Guidance for Determining the Size of Each Prohibited Area Adjacent to a Waste Water System Treatment Plant (WWTP)

There are several important considerations for the shellfish authority to consider when establishing the size of each prohibited area adjacent to a WWTP discharge:

- (1) The area is large enough to ensure that there is adequate dilution for the type of classification that will be used adjacent to the prohibited area. If a conditional classification (either conditionally restricted or conditionally approved) is established adjacent to the prohibited area, adequate dilution should be determined when the WWTP is operating as normal. "Normal" means that the WWTP is operating fully within the plant's design specifications, including design flows; treatment stages; disinfection; as well as compliance with all permit conditions that relate to the WWTPs effectiveness in reducing enteric viruses in discharged wastewater.

Should a restricted area for the purposes of relaying or depuration be established adjacent to the prohibited area, establishing the size of the prohibited area should be based on worst case plant operating conditions. This same consideration would apply for an approved area adjacent to the prohibited area.

Below are several scenarios that could occur and are critical for Shellfish Control Authorities (SCAs) on

evaluating each WWTP when determining appropriate classifications:

(a) Bypassing stage of treatment

A treatment plant should be considered operating outside of normal operation if a treatment stage such as primary or secondary treatment is bypassed which may result in an increased load of solids in the disinfection step and reduce the effectiveness of disinfection. An additional example would be when a WWTP experiences a loss in disinfection and thus the ability to effectively treat the final effluent. SCAs should determine the significance of these types of events and determine appropriate classification for the growing waters adjacent to the prohibited area.

(b) Operating outside design specifications/other types of failures or events

It is not uncommon for a WWTP to periodically experience mechanical failures of equipment that could alter the treatment of sewage. Additionally, a WWTP may also need to periodically perform routine maintenance to the various stages of treatment and may need to temporarily take a portion of a treatment stage off-line for cleaning. Other unexpected maintenance may need to occur. For example cleaning of filters or membranes that have become bio-fouled.

(c) Operating above design flow

Some WWTPs may operate above its design flow and not necessarily bypass any particular stage of treatment. During these events it is typical for WWTP operators to adjust the operation of the WWTP which may include reducing the treatment time in the aeration stage and/or solids separation/settling stage of treatment. Under some circumstances this could lead to a significant reduction in the effectiveness of disinfection. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these type of events.

(d) WWTP permit violations

If a WWTP is exceeding the permitted bacterial indicator levels in the final effluent this indicates that effectiveness of the disinfection step has been reduced. Other

measured parameters in the effluent (e.g. Total Suspended Solids (TSS), Biochemical Oxygen Demand (BOD)) may also indicate a reduction in treatment efficiency has occurred. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these types of events.

Compliance of WWTP operation permit compliance does not necessarily eliminate the potential transmission of pathogens present in wastewater effluent to contaminating shellfish in the impacted area.

There could be situations in which a particular WWTP could be in compliance with a permit, and could still pose a risk to the shellfish harvest area. For example, a WWTP may have permit conditions to allow for flow blending during high flow periods where a portion of the sewage may receive full treatment but a portion of the sewage may only be partially treated and “blended” in the final disinfection step. Although this may be an acceptable practice under a permit it could result in conditions in which the efficiency of the WWTP to remove enteric viruses is considerably reduced. SCAs may consider assessing the efficiency of WWTPs to determine the significance of these events.

(2) The integrity of the collection system. Collection system malfunctions, bypasses or other factors can lead to significant leakages of untreated sewage to the marine environment.

(3) That there is adequate detection and response time when a malfunction occurs to ensure that all harvesting ceases and closures are enforced, so that contaminated product does not reach the market.

F. Guidance for the Use of MSC in Shellfish Meats in determining the size of the prohibited area impacted by WWTP discharge.

MSC has been demonstrated to accurately assess enteric virus dynamics through contaminant mitigation strategies such as relay. MSC levels in shellstock from growing areas adjacent to WWTP discharge are a function of WWTP performance, seasonal persistence of viruses in the environment and the shellfish, species-specific anomalies, and distance from the outfall. The regulatory level of 50 PFU/100gm is a conservative value used for

re-opening approved growing areas (after 7 days) after a sewage spill and end point target values for viral relay. Before using MSC for these purposes, the Authority should perform preliminary studies to familiarize themselves with the seasonal viral persistence patterns, regional and species-specific anomalies.

Seasonal persistence of MSC in shellfish meats can vary greatly from warm summer months to the cooler fall, winter, and spring months. MSC levels can be 2 to 3 logs (100 to 1000) higher in the late fall, winter, and early spring months demonstrated by multiple studies from conducted in northern temperate latitudes using both MSC and molecular enumeration using PCR for enteric viruses. This dramatic tendency to accumulate virus particles by 2 to 3 logs over the winter months has species-specific implications for warm-water adapted species such as American oysters and northern quahogs, which tend to shut down as cooling water temperatures approach 10°C. Viruses and bacteria bio-accumulated in shellfish behave very differently; FC is prone to die-off in a week or two over colder months while viruses can persist at high levels under these cold water conditions for months. Cold-water adapted species such as soft-shelled clams, Pacific oysters, European oysters, and mussel all demonstrate the tendency to increase by 2 to 3 log values over the colder months.

If the Authority is interested in using MSC in shellfish meats, it is recommended that monthly samples be taken over the course of a year in multiple growing areas inside the 1000:1 line to understand these seasonal, spatial, and species-specific variations. This data can be very useful to assess the feasibility of using the conditionally restricted classification for the purpose of relay.

G. Use of MSC in Evaluating WWTP Efficiency

At a minimum, MSC may be used in conjunction with conventional bacterial indicators to conduct a comprehensive assessment of WWTP microbiological performance. The differences between influent, pre-disinfection effluent, and final effluent samples taken under normal and challenged conditions can be used to assess the viral deactivation efficiency of a specific waste water treatment process. The analysis is somewhat similar to the determination of WWTP efficacy using bacterial indicators such as E. coli, which is currently used to comply with EPA's National Pollution Discharge Elimination System (NPDES) permit requirements for municipal wastewater treatment plant discharge. Many studies have shown that deactivation of bacterial and viral indicators (and pathogens) can be significantly different in different treatment processes and under challenged conditions. There are several case studies showing that under

certain conditions, differential bacterial indicators may indicate highly effective treatment of wastewater while differential MSC samples show little deactivation efficiency.

By collecting differential wastewater samples including influent, pre-disinfection effluent, and final effluent and evaluating these samples for MSC, the viral performance of the wastewater treatment process can be determined. If a comprehensive sampling program includes sufficient samples to assess the WWTP under typical operating conditions as well as challenged condition such as high flow, the viral efficiency of the WWTP can be determined. A comprehensive assessment of WWTP microbiological performance using MSC as well as the conventional bacterial indicators can inform the SSCA on the risk associated with a growing area adjacent to a WWTP outfall. An assessment of a WWTP must demonstrate the range of effluent quality during routine operation through an appropriate sampling study and the ability to accurately predict those times when effluent microbiological quality is detrimentally impacted by challenged conditions.

H. Public Health Significance

The positive relationship between disease and consuming contaminated shellfish has been clearly established. Prevention of consumption of contaminated shellfish is the primary objective of the NSSP. The prohibited area classification is the most restrictive growing area classification and is used for areas subject to gross pollution. The use of this classification is also required for all growing areas immediately adjacent to a wastewater treatment plant and where the shellfish authority has not performed a sanitary survey. The harvesting of shellstock is not allowed for any human food use. For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance, Depletion and Gathering of Seed (Chapter IV @.03 E. Prohibited Classification (2) (a) & (b) and Chapter VI .03 Seed Shellstock A. & B.)

A growing area is placed in the prohibited classification when the sanitary survey or marine Biotoxin surveillance program indicates that fecal material, pathogenic microorganisms, poisonous or deleterious substances, marine Biotoxin, or radionuclides may reach the harvest area in excessive concentrations. The NSSP Model Ordinance also requires that a growing area for which there is no sanitary survey be placed in the prohibited classification as a precautionary measure. Taking shellstock from a prohibited area

for any human food purpose is not allowed.

The NSSP Model Ordinance also requires that an area classified as prohibited must be established between any sewage treatment plants or other waste discharge of public health significance and any growing area placed in the approved, conditionally approved, restricted, or conditionally restricted classification. The size of the prohibited area should be based on the effectiveness and level of sewage treatment; the location of the shellstock resource that would be affected; the classification of adjacent waters, the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; the time it would take the Authority to issue a notice to stop shellstock harvesting, and the degree of effluent dilution. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night.

I. Establishment of Boundaries for the Prohibited Area

The establishment of the boundary for the prohibited area is dependent upon other classification which may be adjacent to the prohibited area. Examples could include water bodies in which the Authority chose to use all five (5) classifications or a situation where the Authority only uses prohibited and approved. The decision of adjacent classifications is often based on shellfish uses for the water body or environmental control and protection efforts by State Water Control Agencies. The requirements of the classification adjacent to the prohibited area and the allowable uses in the areas will often dictate the distance the boundary line for the prohibited area is from the outfall.

Guidance for Dilution Ratios

To determine the impact of a WWTP on adjacent waters, it is imperative that the Shellfish Control Authority assess the waste water dispersal and dilution and the time of transport to the area where shellstock may be harvested. In determining the appropriate dilution for establishing the size of the prohibited area, the Shellfish Control Authority must determine the classification which will be adjacent to the prohibited area. The dilutions below outlines recommended dilution for the boundary line between prohibited and other possible classifications based on dilutions of WWTP effluent, based on initial FC values of 1.4×10^6 FC/100ml.. Each of these dilutions will be discussed in more detail in the context of each classification.

- (1) Prohibited to Restricted Boundary
Minimum dilution – The SCA should determine the effluent quality based on a worst case scenario and should establish a dilution ratio that would accomplish a dilution equivalent to a MPN of 88 (or 163) which is the upper limit restricted standard for depuration and relaying without a contaminant reduction study.

- (2) Prohibited to Conditionally Restricted Boundary
Minimum dilution of 320:1 based on "Critical Dilution for Toxics to Ambient (Background)" from the Clean Water Act and EPA's Regulatory Mixing Zone (RMZ).

- (3) Prohibited to Conditionally Approved Boundary
Minimum dilution 1000:1 or justified by other data.

- (4) Prohibited to Approved Boundary
Minimum dilution >100,000:1 dilution based on worst case scenario or justified by other data.

V. Restricted Classification.

A. Definition

A classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.

B. Requirements for Use of the Restricted Classification

- (1) Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification

A. General...

B. Approved Classification...

C. Conditional Classifications...

D. Restricted Classification.

(1) General

(a) A growing area may be classified as restricted when:

(i) A sanitary survey indicates a limited degree of pollution; and

(ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such

levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.

(b) The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:

(i) By special license; and

(ii) Under the supervision of the Authority.

(2) Water Quality. Water quality in the growing area shall meet the bacteriological standards in Section @.02 for a growing area in the restricted classification if the growing area is used for depuration. (These standards are included later in this section.)

(3) Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:

(a) Chapter V. Shellstock Relaying;

or

(b) Chapter XV. Depuration

E. Prohibited Classification...

C. Allowable Uses of Shellfish from a Restricted Growing Area

(1) Relay with a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(2) Relay without a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the

treatment process.

(3) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(4) Seed

Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Relaying with a Contaminate Reduction Study

(1) Chapter V. Shellstock Relaying

@.01 General

The Authority shall assure that:

A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;

B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;

C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by total coliform or fecal coliform or poisonous or deleterious substances that may be present in shellstock. For shellstock harvested from areas impacted by waste water system discharge, MSC may be used as a measure for viral reduction.

D. If shellstock are relayed in containers:

(1) The containers are:

(a) Designed and constructed so that they allow free flow of water to the shellstock; and

(b) Located so as to assure the contaminant reduction required in Section C.; and

(2) The shellstock are washed and culled prior to placement in the containers.

@.02 Contaminant Reduction.

- A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.
- B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:
 - (1) The microbiological quality of each shellfish species is the same microbiological quality as that of the same species already present in the approved or conditionally approved area; or
 - (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels; or
 - (3) When the source growing area is impacted by waste water system discharge, the viral quality of each shellfish species meets the male-specific coliphage standard of 50 PFU/100 gm or predetermined levels established by the Authority based on studies conducted on regional species under regional conditions.
- C. The authority may waive the requirements for a contaminant reduction study if:
 - (1) Only microbial contaminants need to be reduced; and
 - (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and
 - (3) The treatment period exceeds sixty (60) days.

D. The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.

E. When container relaying is used and the Authority allows a treatment time of less than fourteen (14) days, the Authority shall require more intensive sampling including:

(1) Product sampling before and after relay; and

(2) Monitoring of critical environmental parameters such as temperature and salinity; and

(3) For SSCAs using male-specific coliphage, monitoring before and after relay for shellstock relayed from areas impacted by waste water system discharge.

F. The Authority shall establish the time period during the year when relaying may be conducted.

In addition to the requirements of Chapter IV. @.02 G. & H., restricted growing waters used for relaying without a contaminant reduction study must meet the requirements of Chapter IV. @.03 D.

E. Guidance for Restricted Classification for Relaying with a Contaminant Reduction Study

Model Ordinance Chapter IV and V do not include microbial standards for classifying growing areas as restricted that are the source of shellstock for relaying when a contaminant reduction study is required. In establishing of the boundary between prohibited and restricted classifications, the Authority must ensure that levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.

In determining an appropriate boundary, the Authority shall consider the following factors associated with the wastewater discharge:

(1) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent.

- The Authority may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;
- (2) The decay rate of the contaminants of public health significance in the wastewater discharged;
- (3) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
- (4) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

A growing area may be placed in the restricted classification instead of the prohibited classification when the sanitary survey indicates a limited degree of pollution. This option may be used when the sanitary survey for the growing area indicates that the microbiological quality or poisonous or deleterious substances in the growing area are such that additional treatment through relay can render the shellstock safe for human consumption. The Authority should use the restricted classification only when sufficient relay studies have been conducted to establish raw product quality requirements at the harvest level; and when the Authority has sufficient administrative and technical resources to properly administer this classification. These resources include monitoring of pollution sources; providing coordination between state, local and industry officials; issuing special harvesting permits; and supervising the harvesting and transport of shellstock to relay sites. For a complete discussion of the supervision requirements at the harvest level, see the NSSP Guidance Document, Shellstock Relay (ISSC/FDA, 2015).

Use of the restricted classification for relaying with a contaminant reduction study requires the Authority to develop the controls necessary to assure that the shellfish are relayed prior to consumption. The criteria may vary according to the use to be made of the shellstock and the effectiveness of the relay process used to cleanse the shellstock. Process effectiveness is determined through a study, which establishes the levels of microbiological quality indicators in shellstock at the time of harvest, and the density that can be achieved at the completion of the process. Effectiveness of the process is likely to vary between growing areas used for natural cleansing treatment in relay operations. The species of shellstock may also affect the effectiveness of the relay. For a complete discussion of relay, see the NSSP Guidance Document, Shellstock Relay (ISSC/FDA, 2015).

F. Guidance for Conducting a Contaminant Reduction Study for Relay

The use of the restricted classification for the purpose of relaying with a contaminant reduction study does not require the authority to demonstrate that the growing area meets a microbiological water quality standard. However, in determining the boundary between the prohibited area and the restricted area for relaying with a contaminant reduction study, the authority shall give consideration to the types of contamination that may be in the growing area prior to allowing the area to be in the source of shellfish for relaying. The contaminants may include:

- Pathogenic Organisms
- Poisonous or Deleterious Substances
- Marine Biotoxins
- Physical and Chemical Contaminants

Contaminant Reduction is a specified activity defined in Chapter V. Shellstock Relaying @.02. The authority shall establish species-specific critical values for water temperature, salinity and other environmental factors such as dissolved oxygen and turbidity which may affect the natural treatment process (e.g. relay process). These critical values must be monitored and the Authority shall establish the time of year when relay may be conducted. The relay process requires that shellstock are held in the receiving growing area for a sufficient time under adequate environmental conditions to allow reduction of pathogens as measured by total coliform or fecal coliform. To verify the effectiveness of a relay process, contaminant reduction studies are required. The only exception to this requirement is when water quality in the restricted growing area meets Chapter IV.@.02 G-H, only microbial contaminants need to be reduced, and the treatment period exceeds sixty (60) days. For all other relay operations, the Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the receiving growing area. The receiving waters shall be monitored with sufficient frequency to identify when limiting critical values may be approached. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study shall demonstrate that after the completion of the relay activity, the microbiological quality of each shellfish species is the same microbiological quality as that of the same species already present in the approved or conditionally approved area or contaminants levels of poisonous or deleterious substances in shellstock do not exceed NSSP tolerance levels. Based on the study, the Authority shall establish the time period during the year when relaying may be

conducted. Shellstock shall be relayed for at least fourteen 14 consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated with the contaminant reduction study to be adequate. If the shellstock are container relayed and the treatment times are less than 14 days, intensive sampling is required. This intensive sampling includes lot sampling before and after relay as well as monitoring of critical environmental parameters such as seawater temperature and salinity.

Although minimum requirements for contaminant reduction studies have not been specified in the Model Ordinance, there are certain principles of process verification studies that should be considering including; study design, sampling replicates, and data analysis providing statistical reliability. Shellstock and water samples collected during a contaminant reduction study must be analyzed in NSSP-conforming laboratories using NSSP-approved methods. Shellfish samples should be collected at regular intervals from both source and receiving growing areas over the time period of the relay and the natural cleansing process that is proposed. It is important to produce a sufficiently robust database to demonstrate the process is consistently working and the variables affecting the cleansing process are understood. All shellfish samples of 10 to 12 animals should be collected in triplicate so that the mean as well as standard deviation or standard error can be calculated. Water temperature and salinity should be measured at both source and receiving waters at the time of shellstock collection. Fecal coliform levels of shellstock already present in the receiving growing area should be collected in triplicate and evaluated for comparison to relayed shellstock microbial levels. Contaminant reduction studies are specific to species, source growing area, and receiving growing area. In states with extensive experience with relay practices, the Authority may approach contaminant reduction studies on a more regionally basis covering multiple source and receiving growing areas.

When the source growing area is adjacent to a WWTP outfall, the authority may utilize MSC in conducting the contaminant reduction study. Should the Authority utilize MSC sampling, the MSC levels in each shellfish species after the relay process must be assessed. The male-specific coliphage (MSC) standard of 50 PFU/100gm or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions are both approved for these assessments. Relay dynamics for bacterial and viral pathogens can be very different and assessing both offers more insight into the potential health risk. Seasonal persistence of bio-accumulated viral particles in

shellfish can range 1,000 times higher in the winter months verses the summer months. Depuration rates can vary from 1 log in 44 hours at receiving water temperature above 18°C to 1 log in 25 days when receiving water temperature fall below 10°C. Understanding these dynamics for each species and region is paramount to successful relay from restricted or conditionally restricted growing areas adjacent to WWTP outfall. When container relaying is considered and treatment times of less than 14 days are planned, an intensive MSC sampling program based on before and after relay samples can be utilized to assure relayed shellstock are less than the 50PFU/100gm standard or pre-determined levels established by the authority based on studies conducted on regional species under regional conditions.

G. Guidance for the use of MSC in Contaminant Reduction Studies and Process Control for Shellstock Relay

MSC has been shown to be an appropriate modeling organism for contaminant reduction studies and process verification for shellstock from growing areas impacted by a WWTP outfall. The ability of MSC to model enteric viral dynamics in relay and depuration has been demonstrated in several studies using different species in different parts of the northern temperate zone. The MSC standard of 50 PFU/100gm used in process end-point samples was shown to be conservative with respect to public health outcomes.

The conditionally restricted classification recommended for relay adjacent to WWTP outfalls where contaminant studies will be used, should have limits such as zero-hour maximum MSC limits in the shellstock from the source growing areas, seasonal limits, and receiving water temperature and salinity limits as determined by comprehensive contaminant reduction studies. This is in addition to controls to assure the continued operation of the adjacent WWTP under the management plan to keep the source growing area in the restricted status. MSC data from sampling shellstock from the source growing area may help determine those times when viral loading and/or viral persistence in the shellstock are low and viral mitigation strategies are feasible. In both viral depuration and viral relay pilot studies using soft-shelled clams in Maine, periods of time were identified using bi-weekly MSC assays of the target species to understand those times when bio-accumulated MSC levels in the shellstock were at a seasonal low (low viral persistence). Receiving waters temperatures were correspondingly high in those summer months resulting in significantly higher depuration rates, especially when water temperature exceeded 64.4°F (18°C). Studies showed the

deuration rate approached a single log reduction in 44 hours when water temperatures were above 64.4°F (18°C). In contrast, those studies also determined that as water temperature approached 41°F (5°C), it would take approximately 20 days to see a comparable single log reduction in MSC levels. The combination of seasonally low MSC levels in the soft-shelled clams and higher summertime deuration rates resulted in successful deuration consistently meeting a shellfish end-point of 50 PFU/100gm.

Species-specific and regional anomalies in persistence and relay and deuration dynamics require that comprehensive contaminant reduction studies be performed for each growing area for each relay or deuration process being considered. In planning a comprehensive contaminant reduction study, sufficient quantities of target specie(s) from the source area should be collected on a regular basis and evaluated for fecal coliform and MSC (triplicate samples of 10-12 animals), during that period of time when the restricted harvest is being considered. Background levels of MSC are not known in a new species or region, the Authority might consider collecting samples year round in the first year to understand the range of viral persistence throughout the year to understand those times when viral mitigation strategies are feasible.

Trial lots of shellstock should be evaluated monthly during the period of time when the relay is being considered. One to two bushels are adequate for relay trials. Triplicate shellfish samples of 10 to 12 animals from the approved relay site should be collected at appropriate intervals and analyzed for fecal coliform and MSC. Contaminant reduction studies should use triplicate samples so that variation as well as mean value can be assessed yielding improved statistical reliability for the contaminant reduction studies. If little is known about the deuration rates of the target species, it may be necessary to conduct a separate study using shellfish that are highly contaminated with MSC to assess the viral deuration rate in that region. The goal of contaminant reduction studies is to show those periods of time and the conditions when relay is effective.

The Authority may permit an end-point value other than 50 PFU/100gm based if pre-determined levels established by the Authority based on studies conducted on regional species in regional conditions are known.

H. Model Ordinance Requirements for Relaying without a Contaminant Reduction Study

(1) Chapter V. Shellstock Relaying

@.01 General

The Authority shall assure that:

- A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted.
- B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;
- C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by total coliform or fecal coliform. For shellstock harvested from areas impacted by waste water system discharge, MSC may be used as a measure for viral reduction, or poisonous or deleterious substances that may be present in shellstock.
- D. If shellstock are relayed in containers:
 - (1) The containers are:
 - (a) Designed and constructed so that they allow free flow of water to the shellstock; and
 - (b) Located so as to assure the contaminant reduction required in Section C.; and
 - (2) The shellstock are washed and culled prior to placement in the containers.

(2) Chapter V. Shellstock Relaying

@.02 Contaminant Reduction

- C. The Authority may waive the requirements for a contaminant reduction study if:
 - (1) Only microbial contaminants need to be reduced; and
 - (2) The shellstock are relayed from a conditionally approved, restricted, or

conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and

(3) The treatment period exceeds sixty (60) days

(3) Chapter IV. Shellstock Growing Areas

@.02 Microbiological Standards

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section G. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

(a) 300 MPN per 100 ml for a three-tube decimal dilution test;

(b) 173 MPN per 100 ml for a twelve-tube single dilution test; or

(c) 163 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection. Samples shall be collected in accordance with Section E. (3).

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.

- (2) Pollution Sources. Growing areas shall meet the requirements in Section F. (2).
- (3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (4).
- (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:
 - (a) 260 MPN per 100 ml for a five-tube decimal dilution test;
 - (b) 300 MPN per 100 ml for a three-tube decimal dilution test; or
 - (c) 163 CFU per 100 ml for a MF (mTEC) test.
- (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section F. (5).
- (6) Required Sample Collection.
 - (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section G. (2).
 - (b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in Section F. (6) for the application of the standard under Section H. (4).

In addition to the requirements of Chapter IV @.02 G & H., restricted growing waters used for relaying without a contaminant study must meet the requirements of Chapter IV @.03 D. (Page 12)

I. Guidance for Restricted Classification for Relay Without a Contaminant Reduction Study

The NSSP Model Ordinance provides state Authorities the option to allow relaying from a restricted area affected by a point source without a contaminant reduction study. The requirement for establishing the restricted classification for this use is different than the requirements for relay with a contaminant reduction study. The Authority must assure that the bacteriological quality of every station meets Chapter IV @.02 G (2). Additionally, the treatment period must exceed sixty (60) days. Should the Authority have viral concerns, the use of MSC sampling of the shellfish would be appropriate. The Authority could use the 50 PFU/100gm level or predetermined levels established by the Authority based on studies conducted in the area.

J. Model Ordinance Requirements for Depuration

(1) Chapter IV. Shellstock Growing Areas

@.02 Microbiological Standards.

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section G. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

(a) 300 MPN per 100 ml for a three-tube decimal dilution test;

(b) 173 MPN per 100 ml for a twelve-tube single dilution test; or

(c) 163 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection. Samples shall be collected in accordance with Section E. (3).

H. Standard for the Restricted Classification of

Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.

- (1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.
- (2) Pollution Sources. Growing areas shall meet the requirements in Section F. (2).
- (3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (4).
- (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF(mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:
 - (a) 260 MPN per 100 ml for a five-tube decimal dilution test;
 - (b) 300 MPN per 100 ml for a three-tube decimal dilution test; or
 - (c) 163 CFU per 100 ml for a MF (mTEC) test.
- (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section F. (5).
- (6) Required Sample Collection.
 - (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section G. (2).
 - (b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in Section F. (6) for the application of the

standard under Section H. (4).

(2) Chapter XV. Depuration

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall...

(2) The dealer shall...

(3) Should a dealer...

(4) The dealer shall receive and depurate only shellstock obtained from a special licensed harvester who has:

(a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status.

(b) Identified the shellstock...

K. Guidance for Restricted Classification for Depuration

Use of the restricted classification for depuration requires the Authority to conduct a sanitary survey of the growing area as required in Chapter IV @ 01 and establish a monitoring program to ensure the water quality requirements of Chapter IV @ 02 G & H and @03 D.

Depuration process verification described in Chapter XV. @.03 Section J. is based on conditional and approved protocols. The protocol is conditional when statistical analysis of the database containing the 10 most recent FC end point samples fails to meet prescribed species-specific indices. The intent of which is to ensure an appropriate level of testing and quality assurance, including release criteria, during those periods of time when the depuration process is being challenged. These process verification protocols are based on fecal coliform assays of shellfish meats. The requirement for adverse case sampling of the restricted growing area is to assure that water quality in the restricted harvest growing areas does not exceed a median FC score of 88/100ml (or 163 FC.100ml) and P90 requirements.

Water quality requirements for the restricted growing area used for depuration were put in place to prevent grossly contaminated shellfish from being processed. It was not the inability to depurate high FC levels from contaminated shellstock, but rather that viruses associated with grossly contaminated shellstock were

thought to not effectively deplete viruses in 44 hours. In contrast, restricted growing areas adjacent to WWTP discharges used for relay with contamination reduction studies are considered effective for viral reductions and do not require a water quality sampling program based on 14 consecutive days of relay. The inability to detect viruses using fecal coliform based process verification and the lack of any suitable viral indicator assays was the original rationale behind restricted growing areas for depuration requiring water quality limits.

L. Model Ordinance Requirements for Use of a Restricted Area as the Source of Seed

(1) Chapter VI. Shellfish Aquaculture

.03 Seed Shellstock

Seed may come from any growing area, or from any growing area in any classification, provided that:

- A. The source of the seed is sanctioned by the Authority; and
- B. Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of six (6) months.

M. Seed

If a restricted growing area is used as a source for seed and the Authority requires that the shellfish must be cultured in the approved growing area for a minimum of six (6) months, the classification requirements for relay and depuration are adequate for this use.

N. Determination of the Boundaries Between Prohibited and Restricted Areas

The establishment of boundaries separating prohibited and restricted growing areas is dependent upon the uses to be allowed within the restricted growing area. MO Chapters IV and V address the classification requirements for allowable shellfish uses in the restricted classification. These uses include the following:

- (1) Relay with a contaminant reduction study
- (2) Relay without a contaminant reduction study
- (3) Depuration

If harvesting for relay with a contaminant reduction study, the

boundary line should be based on an acceptable dilution ratio. If harvesting for relay without a contaminant reduction study or depuration, the boundary line must be based on a fecal coliform sampling program. The SCA has the option to utilize MSC.

Guidance for Dilution Ratios

Restricted areas that are the source for shellstock relaying with a contaminant reduction study are not required to meet a microbiological standard. Shellstock from restricted areas used for relaying without a contaminant reduction study or for depuration do have to meet a microbiological standard. In the absence of a microbiological standard, dilution ratios become very important to protect public health. A Shellfish Control Authority should not allow relay with a contaminant reduction study from any portion of a restricted area that does not meet a minimum dilution. The SCA should determine the effluent quality based on a worst case scenario and should establish a dilution ratio that would accomplish a dilution equivalent to a MPN of 88 (or 163) which is the upper limit restricted standard for relaying without a contaminant reduction study and for depuration. This dilution is 16,000:1. Should the Shellfish Control Authority choose to classify waters not meeting a dilution ratio equivalent to the upper limit MPN standard of 88 (or 163), the classification should be supported by fecal or MSC sampling of WWTP effluent to demonstrate a wastewater quality level less than 1.4×10^6 or the results of the contaminate reduction studies conducted over worst-case scenarios at the upstream WWTP discharge.

VI. Establishment of Conditional Classifications

The basic concept of the NSSP is to control the safety of shellfish by preventing their harvest from contaminated growing areas. In reviewing growing area classifications and sanitary surveys conducted by Shellfish Control Authorities, it appears that a common misinterpretation is the classification of an area as approved when in fact the area should have been classified as conditional. Critical investigations usually reveal that the area is subject to intermittent pollution events. Careful consideration of an intermittent pollution event, development and application of a management plan, and cooperation and compliance by all parties may also allow upgrading of an area to a conditionally approved or conditionally restricted classification instead of requiring the area to be restricted or prohibited at all times.

Intermittent pollution to shellfish growing waters has been a significant cause of shellfish-borne infectious disease outbreaks worldwide. In 1978, at least 20,000 persons were involved in an outbreak of oyster-associated gastroenteritis attributed to Norwalk virus. The investigation of the outbreak indicated that a combination of meteorological and hydrographic

events had caused inadequately treated and diluted sewage from a nearby municipal facility to reach the area. In an incident in 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters when a combination of raw sewage bypasses, high rainfall, strong winds, and abnormally low tides caused contamination of an area that was classified as approved. In both of these instances, application of the conditionally approved area concept probably could have prevented the outbreaks.

A common situation where this classification might be appropriate is when water quality is, to some degree, dependent upon the operation of a Waste Water Treatment Plant (WWTP). For example, the boundaries of an approved shellfish area might be improperly determined during a period when a WWTPSD is operating at a satisfactory level. If there is some interruption in treatment, it follows that there will be some degradation of water quality in the growing area which may require a relocation of the boundaries. The degree of relocation would depend upon such items as the distance between the pollution source and the growing area, hydrography, the amount of water, and the amount of pollution.

The first step in determining whether an area should be classified as conditionally approved or conditionally restricted is to determine whether sufficient State resources are available to manage, survey, monitor, control harvesting, affect closures, and reopen the area as required. It should be noted that sources of pollution must be routinely monitored; coordination between State, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. States electing to classify areas as conditionally approved have found the public resource investment to be substantial.

The second step in determining whether an area should be placed in the conditionally approved or conditionally restricted classification is to evaluate the potential sources of pollution in terms of their effect on water quality in the area. Potential sources of pollution involving a WWTP include: bypasses and overflows within a sewage collection and treatment system.

The third step in establishing a conditionally approved or conditionally restricted area is to evaluate the source of pollution in terms of the water quality standards to be maintained, and to formulate performance standards for each pollution source having a significant effect on the sanitary quality of the area. The following is an example of performance standards that might be developed:

Performance standards or closure criteria may be based upon the bacteriological quality of effluent from sewage treatment plants. This

might be stated in terms of chlorine residual if the bacteriological quality of the effluent can be positively related to chlorine residual. The following is an example of a performance standard for an effluent discharge: "The median coliform MPN, in any one (1) month, shall not exceed 500 per 100 ml, based on not less than sixteen (16) composite samples per month, and not more than ten (10) percent of the samples shall have an MPN in excess of 10,000 per 100 ml. Determinations of the chlorine residual of the effluent should be made hourly and recorded in the permanent plant records."

A performance standard may be based upon total quality of sewage, which can be discharged from any given unit, or from a combination of units, without causing the basic water quality standards to be exceeded.

The design of a waste treatment plant and the plant effluent specifications may be critical to the designation of an area classified as conditionally approved or conditionally restricted. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (coliform) of sewage, predicted survival of coliform in seawater, effectiveness of chlorination and the total quality of clean dilution water in an area. Results of many studies on the survival of bacteria in seawater have been published.

The mechanical equipment at critical sewage treatment or pumping units should be such that interruptions will be minimized. Wherever possible, operations should be automatically recorded on charts. Requirements that might be imposed depend upon the importance of the unit's relationship to water quality. Important design features of a sanitary waste collection system that should be considered include:

Storm water should be excluded from the sanitary system. There should be stand-by equipment to insure that treatment or pumping will not be interrupted. It should be taken into account that interruptions may occur because of damage to a single unit or a power failure.

The pumps and critical units should be fitted with meters or gauges so the regulatory agency can monitor performance standards.

Installation of recording scales to indicate rate of chlorine use is helpful. Chlorine flow meters are available that integrate hydraulic flow with chlorine demand.

Liquid level recording gauges fitted with alarms and located in overflow channels of sewage treatment plants and wet wells of lift stations are useful. They can be set to indicate when overflow takes place. It is good operating procedure to date recording charts. Gauges should be calibrated and maintained so that indicated discharge rates are accurate.

Automatic devices to warn of failure or malfunctioning at self-operated pumping stations or treatment plants can be an important control.

Another factor to consider in developing a conditionally approved or conditionally restricted area is that a prohibited area must be interposed between the conditionally approved or restricted area and the source of pollution. The size of such area should be based on the total time it would take for the operating agency to detect a failure, notify the State Shellfish Control Agency, and for the latter agency to issue a notice to stop shellfish harvesting. It is recommended that the area be of such size that the flow time through the safety area is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that closure actions might be necessary on holidays or at night.

The length of time a conditionally approved or conditionally restricted area should be closed following a temporary closure will depend upon several factors including the species of shellfish, water temperature, shellfish activity and cleansing rates, presence of silt or other chemicals that might interfere with the physiological activity of the shellfish, and the degree of pollution of the area.

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These optional classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection and the control of shellfish safety in the use of the conditional classifications are afforded through the use of a management plan. The management plan for each growing area placed in a conditional classification is based on the information gathered during the sanitary survey. The plan establishes a strict set of criteria that must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two (2) of the most important components of the management plan are: the acceptance of and the agreement to the conditions of the management plan by the one (1) or more Authorities involved, other local, State and Federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of compliance with the plan to assure public health protection. Use of the conditional classification requires more intense monitoring and more frequent reevaluation because of the intermittent nature of the pollution event.

When the Authority has sufficient resources to manage a conditional

classification, the use of the conditional classification could allow the safe use of growing areas that might otherwise not be available to the shellfish industry. For a complete discussion of the conditional classification, see the NSSP Model Ordinance Guidance Documents: Management Plans for Growing Areas in the Conditional Classification (ISSC/FDA, 2015). For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: Sanitary Survey and the Classification of Growing Waters (ISSC/FDA, 2015).

A. Requirements for Conditional Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(1) Survey Required. The sanitary survey meets the following criteria:

(a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;

(b) Each potential source of pollution that may adversely affect the growing area is evaluated;

(c) Microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and

(d) For SSCAs utilizing MSC meat sample data, this data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.

(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:

(a) For management plans based on wastewater treatment plant function, performance standards that include:

- (i) Peak effluent flow, average flow, and infiltration flow;
- (ii) Microbiological quality of the effluent;
- (iii) Physical and chemical quality of the effluent;
- (iv) Conditions which cause plant failure;
- (v) Plant or collection system bypasses;
- (vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
- (vii) Provisions for monitoring and inspecting the waste water treatment plant; and
- (viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;

(b) For management plans based on pollution sources other than waste water treatment plants:

- (i) Performance standards that reliably predict when criteria for conditional classification are met; and
- (ii) Discussion and data supporting the performance standards.

(c) For management plans based on waste water system discharge function or pollution sources other than waste water system discharge

criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:

(i) Performance standards of the plan are fully met;

(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;

(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels.

Studies establishing sufficient elapsed time shall document

the interval necessary for

reduction of coliform levels

in the shellstock to pre-

closure levels. The study

may establish criteria for

reopening based on coliform

levels in the water. The

SSCA may utilize MSC in

growing areas adjacent to

waste water system

discharge. Studies

establishing sufficient

elapsed time shall

document the interval

necessary for reduction of

viral levels in the

shellstock. Analytical

sample results shall not

exceed a level of 50 MSC

per 100 grams or pre-

determined levels

established by the

Authority based on studies

conducted on regional

species under regional

conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed; and

(iv) Shellstock feeding activity is sufficient to achieve microbial reduction.

(d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;

(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;

(g) Provisions for patrol to prevent illegal harvest; and

(h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.

(3) Reevaluation of Conditional Classification.

(a) The classification shall be reevaluated at least once each year. The reevaluation shall include:

(i) Evaluation of compliance with the management plan;

(ii) Determination of adequacy of reporting of failure to meet performance standards;

(iii) Review of the cooperation of the persons involved;

(iv) Evaluation of water

quality in the growing area with respect to the bacteriological standards for its classification;

(v) Field inspection of critical pollution sources, where necessary; and

(vi) Written findings, evaluations and recommendations.

(b) Water Sample Collection.

(i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.

(ii) When the conditional management plan is based on the operation and performance of a Waste Water System Discharge (WWSD) (s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.

(iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(iv) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, storm water runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status.

(v) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events or storm water runoff, and the area is in the open status for less than six (6) months a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). At least one (1) sample shall be collected each month the area is placed in the open status. This sample shall be collected while the area is open. If closed status samples are used to meet the minimum sample requirements only two (2) sets of samples may be utilized and they must have been taken within five (5) days of when the Authority anticipates that the area will

be placed in the open status. For growing areas in the open status less than two (2) months, at least one (1) sample must be collected while the area is in the open status. Samples collected during the closed status to meet the minimum five (5) sets of water samples shall be applied to annual and triennial reevaluations of the area.

(vi) When the conditional management plan is based on the seasonal opening and closing of the area, and the area is in the open status for a predetermined period of less than six (6) months, a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). All samples shall be collected while the area is in the open status unless the Authority has historical water quality data to demonstrate that the area meets open status criteria while in the closed status. If closed status samples are used to meet the minimum sample requirements they must be collected within thirty (30) days prior to the area being placed in the open status.

(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved.

(a) The management plan shall be

developed by the Authority in coordination with:

(i) The local shellfish industry;

(ii) The individuals responsible for the operation of any Waste Water System Discharge (WWS)Ds involved; and

(iii) Any local or State agencies; and

(b) Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.

(5) Conditional Area Types. There are two (2) types of conditional areas:

(a) Conditionally approved; and

(b) Conditionally restricted

B. Guidance for a Conditional Area Management Plan

The management plan for a growing area in the conditionally approved or conditionally restricted classification must meet certain minimum requirements to ensure that the safety of the shellfish for human consumption is maintained. The use and success of the conditional classification depends upon a thorough and accurate management plan. Therefore, it is important that all aspects of the management plan be fully considered and implemented. The minimum requirements to be addressed are:

(1) An understanding of and an agreement to the conditions of the management plan by the one (1) or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved;

(2) A written management plan for the growing area being placed in the conditional classification, which includes a general description of the growing area with a map showing the area's boundaries, and which addresses all items in C. through H..

- (3) A sanitary survey that shows the growing area will be in the open status of its conditional classification for reasonable periods of time. The survey must provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted, and the supporting information and data.
- (4) A description of the predictable pollution event or events that are being managed and the performance standards established for each pollution source contributing to the pollution event including:
- (a) For a wastewater treatment facility, the performance standard should be based on:
 - (i) Peak effluent flow
 - (ii) Bacteriological quality of the effluent
 - (iii) Physical and chemical quality of the effluent
 - (iv) Bypasses from the treatment plant or its collection system
 - (v) Design, construction, and maintenance to minimize mechanical failure or overloading (i.e., the reliability of the treatment system and collection system components)
 - (vi) Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.
 - (vii) Identification of conditions that lead to Waste Water Treatment Plant (WWTP) failure and closure of the conditionally approved area.
 - (b) For meteorological or hydrological events, the performance standard should be based on:
 - (i) Identification of the specific meteorological and/or hydrologic event that will cause the growing area to be placed in the closed status;

	<p>(ii) <u>Discussion and data analyses concluding that effects on water quality from these specific meteorological and/or hydrologic events are predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for the growing area placed in the conditional classification; and</u></p> <p>(iii) <u>The predicted number of times, based on historical findings, that the pollution event will occur within one (1) year.</u></p> <p>(c) <u>For seasonal events, such as marina operation, seasonal rainfall, and waterfowl migration, the performance standard should be based on:</u></p> <p>i. <u>Identification of the seasonal event that will cause the growing area to be placed in the closed status, including its estimated duration; and</u></p> <p>(ii) <u>Discussion and data concluding that the seasonal event is predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for a growing area placed in the conditional classification;</u></p> <p>(5) <u>A description of the plan for monitoring water quality including numbers and frequency;</u></p> <p>(6) <u>A description of how the closed status for the conditional classification will be implemented, which must include:</u></p> <p>(a) <u>A clear statement that when the performance standards are not met, the growing area will immediately be placed in the closed status;</u></p> <p>(b) <u>A requirement to notify the Authority or Authorities that the</u></p>
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management plan performance standards have not been met, including:

- (i) The name of the agency or other party responsible for notifying the Authority;
- (ii) The anticipated response time between the performance standards not being met and notification of the Authority; and
- (iii) The procedures for prompt notification including contingencies such as night, weekend and absences of key personnel;

(c) A description of the implementation and enforcement, including:

- (i) The response time between the notification to the Authority of the failure to meet performance standards and activation of the legal closure of the growing area by the Authority;
- (ii) The procedures and methods to be used to notify the shellfish industry; and
- (iii) The procedures and methods to be used to notify the patrol agency (enforcement agency) including:

- The name of the responsible patrol agency;
- The anticipated response time between the Authority's legal closure of the growing area and notification of closure to the patrol agency; and
- A description of the patrol agencies anticipated activities to enforce the closed status.

(7) A description of the criteria that must be met prior to reopening a growing area in the closed status, including the need to determine that:

- (a) The performance standards established in the management plan are again fully met;
- (b) The flushing time for pollution dissipation is adequate;

- (c) A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;
- (d) Where necessary, the bacteriological quality of the water must be verified; and
- (e) Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

(8) A commitment to a reevaluation of the management plan at least annually using, at a minimum, the reevaluation requirements in the NSSP Model Ordinance

VII. Conditionally Restricted

A. Definition

A classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.

B. Requirements for Conditionally Restricted Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(7) Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:

(a) Meet the requirements for:

- (i) A restricted classification when the conditionally restricted classification is in the open status; and
- (ii) A prohibited classification when the conditionally restricted classification is in the closed status; and

(b) Designate in its management plan whether the harvested shellstock are to be relayed or

depurated.

(2) Use of the conditionally restricted classifications by the Authority is optional. The conditionally restricted classification is designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the prohibited classification year round when, under certain conditions, the shellstock from the growing area may be safely harvested for restricted purposes. The concept also applies to situations where conditions are acceptable for harvest when wastewater treatment plant operation is satisfactory, but not when a malfunction occurs. A management plan is required that describes the controls to provide public health protection in the use of the conditionally restricted classification. For a full explanation of the conditional classifications and their use, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2015).

State Control Authorities that allow relaying or depuration may utilize the conditionally restricted classification adjacent to prohibited areas established as a result of a WWTP outfall. The use of the conditionally restricted classification is dependent upon the predictable factors associated with the WWTP discharge. These factors may include volume, treatment efficient, seasonality or other factors which affect the quality of the WWTP effluent. The quality concerns are bacterial, viral, toxic chemical and poisonous deleterious substances. Portions of the prohibited area that are less impacted by the WWTP outfall during predictable time periods can be classified conditional and used as a source of shellfish for relaying and depuration.

The conditionally restricted classification management plan must establish a strict set of criteria, which must be met for the growing area to remain in the restricted status. The following are examples of different types of performance standards that could be used:

(a) Performance standards might stipulate the bacteriological quality of effluent from sewage treatment plants. The

microbiological quality can be monitored in terms of disinfection residual or dosage for ultraviolet light disinfection. An example of a performance standard for an effluent discharge is:

"The median fecal coliform MPN, in any one (1) month, shall not exceed 200 per 100 ml, based on not less than sixteen (16) samples per month, and not more than ten (10) percent of the samples shall have an MPN in excess of 1,000 per 100 ml. This fecal coliform limit shall be presumed to be met if the chlorine residual in the effluent is at least 1.0 ppm and the chlorine residual in the effluent is continuously recorded on a chart by chlorine residual analyzer or is measured hourly and recorded in the daily monitoring records as required for the plant's NPDES permit."

(b) For disinfection by ultraviolet (UV) light, the disinfection is based on dosage. An example of a performance standard is, "A minimum UV dose of 37 mW-Sec/cm² is to be maintained. The calculation of intensity of the UV light is to include factors for effluent quality, including turbidity, suspended solids, and transmittance. The effluent factors contributing to the dose, including turbidity, suspended solids, transmittance, and flow will be continuously measured and recorded. An alarm will be activated if any of the factors are above design limits."

A detailed discussion of ways to increase the reliability of sewage treatment plants can be found in *Protection of Shellfish Waters* (USEPA, 1974) and *Design Criteria for Mechanical, Electric and Fluid System Component Reliability* (USEPA, 1974).

The fourth step is to determine the water quality, which will occur in the growing area when the performance standards are not met, and what portion of the growing area will be affected. Once these determinations are made, the Authority can select the appropriate management strategy for the portion of the growing area

that will be placed in the closed status when performance standards are not met, and can select the boundaries for the closed status. The boundaries of that portion of the growing area to be placed in the closed status would depend upon such items as the distance and travel time from the pollution source to the area, the concentration of pollutants in the discharge during the breakdown condition, amount of effluent and hydrographic factors including dilution available in the receiving water.

The use of the conditional classification where a sewage treatment plant is the pollution source being managed requires a fifth step. An area in the prohibited classification must be established between the sewage treatment plant and the growing area placed in the conditionally approved or conditionally restricted classification. The size of the prohibited area should be based on the level of sewage treatment; the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; and the time it would take the Authority to issue a notice to stop shellstock harvesting. The size of the area in the prohibited classification should allow for an effluent travel time through the prohibited area that is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night. A minimum effluent dilution is to be determined at the prohibited boundary and can be the controlling factor in situations where there is efficient detection and notification of breakdowns.

The length of time that a growing area should be in the closed status of its conditional classification will depend upon several factors. These factors include the degree of pollution in the growing area and flushing capacity of the estuary, the species of shellfish, water temperature, shellstock activity and cleansing rates, and presence of silt or other chemicals that might interfere with the physiological activity of the shellstock. Additional information on the natural cleansing of shellstock is provided in the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2015).

C. Allowable Uses of Shellfish from a Conditionally Restricted Growing Area

(1) Allowable Uses When Area is in Restricted Status

(a) Relay without a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or

conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(b) Relay with a Contaminant Reduction Study

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(c) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(d) Seed

Seed means shellstock which is less than market size.

(2) Allowable Uses When Area is in Prohibited Status

(a) Seed

Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Relay with a Contaminant Study

The Requirements for Relay with a Contaminant Study are defined in Section V. D.

E. Model Ordinance Requirements for Relay without a Contaminant Study

The Requirements for Relay without a Contaminant Study are defined in Section V. H.

F. Model Ordinance Requirements for Depuration

The Requirements for Depuration are defined in Section V.J.

G. Model Ordinance Requirements for Seed

The Requirements for Seed are defined in Section V.L.

H. Determining Boundaries for Conditionally Restricted Growing Areas

Should the Authority utilize the conditionally restricted

classification to allow relay or depuration, the area classified as conditionally restricted would be established within the portion of the prohibited area established adjacent to the WWTP. Shellfish uses allowed in the restricted classification would be allowed in the conditionally restricted area when the plant is operating within the satisfactory conditions outlined in the conditionally restricted management plan. (Chapter IV@ .03 C (2). Use of the conditionally restricted classification for relay without contaminant reductions studies and depuration requires the Authority to determine whether the growing area is impacted by additional point and non-point sources of pollution in addition to the management plan which is intended to address all potential problems with the adjacent WWTP. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Chapter IV.@.02 Section G. (2) or Section H. (3) depending upon whether there is an additional point source or just non-point sources of contamination impacting the conditionally restricted growing area. Sufficient water quality samples shall be collected in accordance with Chapter IV.@.02 Section E. (3) at representative water quality sampling stations throughout the impacted restricted growing area.

The establishment of boundaries separating prohibited and conditionally restricted growing areas is dependent upon the uses to be allowed within the restricted growing area. MO Chapters IV and V address the classification requirements for allowable shellfish uses in the restricted classification. These uses include the following:

- (1) Relay with a contaminant reduction study
- (2) Relay without a contaminant reduction study
- (3) Depuration

If harvesting for relay with a contaminant reduction study, the boundary line should be based on an acceptable dilution ratio. If harvesting for relay without a contaminant reduction study or depuration, the boundary line must be based on a fecal coliform sampling program. The SCA has the option to utilize MSC.

The use of the conditionally restricted classification should not affect other adjacent classifications such as restricted, conditionally approved or approved. The area will be considered in the prohibited status when the management plan criteria are not met.

Guidance for Dilution Ratios

For Shellfish Control Authorities that choose to establish conditionally restricted areas, the operating efficiency of the plant must be a primary consideration. A portion of what might be the standard prohibited area could be classified as conditionally restricted when the WWTP is operating efficiently. An explanation for operating efficiency is included in Section VI paged 26 of this document. Conditionally restricted areas, when meeting the NSSP requirement for the restricted classification, can be used for a source for shellstock relaying with a contaminant reduction study. These areas are not required to meet a microbiological standard. Shellstock from restricted areas used for relaying without a contaminant reduction study or for depuration do have to meet a microbiological standard. In the absence of a microbiological standard, dilution ratios become very important to protect public health.

A Shellfish Control Authority should not consider any portion of a growing area that does not meet a 320:1 dilution ratio as a source for relaying with a contaminant reduction study. The concept of a 320:1 dilution ratio was first documented in a technical paper written by Virgil Carr of FDA. The technical paper was based on studies conducted at WWTP utilizing UV for disinfection.

This study proposed that the prohibited area, could approach the size requirements for Critical Dilution for Toxics to Ambient (Background) from the Clean Water Act. Similarly, the EPA's Regulatory Mixing Zone (RMZ) is 300:1, which is approximately the transition line from near field dilution zone to far field dilution zone where most mixing has already occurred. The 320:1 dilution ratio is needed to assure that poisonous and deleterious substances are not present in high enough concentrations to present a public health concern.

From a pragmatic point of view, dilution from the outfall to the 320:1 line is a dilution factor of 320 while dilution from 320:1 to 1000:1 is a dilution factor of 3.1. This roughly equates to 100 times more dilution of the originate effluent occurring within the 320:1 dilution line than occurs from the 320:1 dilution line to the 1000:1 dilution line. This is an important factor to consider when one is attempting to understand the viral density in growing waters overlying growing areas adjacent to WWTP discharge and the associated risk.

VIII. Conditionally Approved

A. Definition

A classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.

B. Requirements for Conditionally Approved Area Adjacent to a Waste Water Treatment Plant (WWTP)

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(6) Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:

(a) Meet the requirements for:

(i) An approved area classification when the conditionally approved classification is in the open status; and

(ii) A restricted or prohibited classification when the conditionally approved classification is in the closed status; and

(b) If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.

Growing areas are placed in the approved classification when the sanitary survey information and marine Biotoxin surveillance data indicate that fecal material, pathogenic microorganisms, poisonous, or deleterious substances are not present in the growing area in unacceptable concentrations. Shellstock harvested from these growing areas may be sold directly to the public for consumption raw or cooked.

C. Allowable Uses of Shellfish in a Conditionally Approved Growing Area

(1) Allowable Uses when the Conditionally Approved Area is in the Open Status

(a) Direct Marketing

Direct Marketing means the sale for human consumption of shellfish which:

- (i) Does not require depuration or relaying prior to sale; or
- (ii) Has been subjected to depuration or relaying activities

(b) Relay

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(c) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(d) Seed

Seed means shellstock which is less than market size.

(e) Post-Harvest Processing

Post-Harvest Processing means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.

(2) Allowable Uses when the Conditionally Approved Area is in the Closed Status

(a) Relay

Relay means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(b) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(c) Seed

Seed means shellstock which is less than market size.

D. Model Ordinance Requirements for Direct Marketing

There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for direct market.

E. Model Ordinance Requirements for Relay

The Requirements for Relay are defined in Section V. H.

There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for relay.

F. Model Ordinance Requirements for Depuration

There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for depuration.

(1) Model Ordinance Chapter XV. Depuration

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

(1) The dealer shall receive and depurate only shellstock which is obtained from a licensed harvester who has:

(a)Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and

(b)Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and

(c)Harvested the shellstock in compliance with the time/temperature requirements of Chapter VIII. @.02 A. (1), (2) or (3) as determined from records supplied by the harvester described in Chapter VIII. .02 G. (2) [C].

(2) The dealer shall...

(3) Should a dealer...

(4) The dealer shall...

The Requirements for Depuration of shellfish harvested from conditionally approved areas in the closed status are defined in Section V.J.

G. Model Ordinance Requirements for Seed

The Requirements for Seed are defined in Section V.L.

There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for seed.

H. Model Ordinance Requirements for Post-Harvest Processing

There are no classification restrictions on shellfish harvested from conditionally approved areas in the open status for post-harvest processing.

I. Model Ordinance Requirements for Relay with a Contaminant Reduction Study

The Requirements for Relay with a Contaminant Reduction Study are defined in Section V.D.

J. Model Ordinance Requirements for Relay without a Contaminant Reduction Study

The Requirements for Relay without a Contaminant Reduction Study are defined in Section V.H.

K. Determining Boundaries for Conditionally Approved Growing Areas

Should the Authority utilize the conditionally approved classification to allow harvest for direct marketing, the area classified as conditionally approved would be established within the portion of the prohibited or restricted area established adjacent to the WWTP. Shellfish uses allowed in the approved classification would be allowed in the prohibited or restricted area when the plant is operating within the satisfactory conditions outlined in the conditionally approved management plan. (Chapter IV@ .03 C (2)).

In addition to meeting the satisfactory conditions outline in the conditionally approved management plan, the area must also conduct a sanitary survey of the growing area as required in Chapter IV @ 01 and establish a monitoring program to ensure the water quality requirements of Chapter IV @ 02 E. The area will

be considered in the prohibited or restricted status when the management plan criteria is not met.

Guidance for Dilution Ratios

For Shellfish Control Authorities that choose to establish conditionally approved areas for harvest uses allowable within the approved classification, the operating efficiency of the plant must be a primary consideration. A portion of the prohibited or restricted area could be classified as conditionally approved when the WWTP is operating efficiently. An explanation for operating efficiency is included in Section VI page 26 of this document. The minimum dilution of 1000:1 is recommended for establishing a conditionally approved area adjacent to a WWTP. The rationale for the 1000:1 dilution rate was included in Section IV: Guidance Document Chapter II 19., which was adopted by the ISSC in 2015. Conditionally approved areas, when not in the approved status, can be used for a source for shellstock relaying with a contaminant reduction study, shellstock relaying without a contaminant reduction study and depuration. To utilize shellfish for these purposes, these areas are required to meet the Model Ordinance requirements associated with those uses (e.g. restricted water quality standard).

IX. Approved Classification

A. Definition

A classification used to identify a growing area where harvest for direct marketing is allowed.

B. Requirements for Use of the Approved Classification

(1) Model Ordinance Chapter IV. Shellstock Growing Areas

@.03 Growing Area Classification.

B. Approved Classification. Growing areas shall be classified as approved when the following criteria are met.

(1) Survey Required. A sanitary survey finds that the area is:

(a) Safe for the direct marketing of shellfish;

(b) Not subject to contamination from human or animal fecal matter at levels that, in the judgment of the Authority, presents an actual or potential public health hazard; and

(c) Not contaminated with:

- (i) Pathogenic organisms;
- (ii) Poisonous or deleterious substances;
- (iii) Marine Biotoxins; or
- (iv) Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification.

(2) Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in Section @.02.

@.02 Microbiological Standards

E. Standard for the Approved Classification of Growing Areas Affected By Point Sources.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:

- (a) 43 MPN per 100 ml for a five-tube decimal dilution test;
- (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
- (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
- (d) 31 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection.

- (a) A minimum of five (5) samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
- (b) A minimum of the most recent fifteen (15) samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.
- (c) Sample station locations shall be

adjacent to actual or potential sources of pollution.

C. Allowable Uses of Shellfish in an Approved Growing Area

(1) Direct Marketing

Direct Marketing means the sale for human consumption of shellfish which:

- (a) Does not require depuration or relaying prior to sale;
- or
- (b) Has been subjected to depuration or relaying activities

(2) Depuration

Depuration means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(3) Seed

Seed means shellstock which is less than market size.

(4) Post-Harvest Processing

Post-Harvest Processing means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.

D. Model Ordinance Requirements for Direct Marketing

There are no classification restrictions on shellfish harvested from approved areas for direct market.

E. Model Ordinance Requirements for Depuration

The Requirements for Depuration are defined in Section XIII.F. There are no classification restrictions on shellfish harvested from approved areas for depuration.

F. Model Ordinance Requirements for Seed

The Requirements for Seed are defined in Section V.L. There are no classification restrictions on shellfish harvested from approved areas for seed.

G. Model Ordinance Requirements for Post-Harvest Processing

There are no classification restrictions on shellfish harvested from approved areas for post-harvest processing.

H. Determining Boundaries for Conditionally Approved Growing Areas

	<p><u>In establishing boundaries between approved areas and other classifications adjacent to a WWTP, the SCA should consider dilution ratios and the approved area must meet the microbiological standards for approved growing areas.</u></p> <p><u>Guidance for Dilution Ratios</u></p> <p><u>When determining if a WWTP or collection system discharge within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance, if a level of 1.4×10^6 FC/100ml is assumed for a raw sewage release, a 100,000:1 dilution would be required to dilute the sewage sufficient to meet the approved area standard of 14 FC/100ml. If dilution analysis determines that the location of the discharge is such that the dilution of effluent would be greater than 100,000:1 then the WWTP could be considered located outside the zone of influence to the shellfish growing area. Different dilution ratios may be applied depending on the known concentration of sewage, a performance history of the treatment and collection system and a database of influent and effluent quality, provided that the water quality objective of the downstream harvest area is met.</u></p>
<p>Public Health Significance</p>	<p>In 2015, the ISSC adopted proposal 15-102 which incorporated the use of Male Specific Coliphage into the NSSP. The ISSC voting delegates directed the development of a guidance document to provide clarification for the use of MSC. This guidance document provides guidance regarding the use of MSC in the classification of shellfish growing areas adjacent to waste-water treatment plants. The classification guidance provides details and clarification that shellfish Authorities should find very helpful.</p>
<p>Cost Information</p>	