Proposal Subject: Dilution Guidance for Prohibited Zones Associated with Wastewater Discharges

Specific NSSP Guide Reference: NSSP Guide Section IV. Guidance Documents
Chapter II. Growing Areas

Text of Proposal/ Requested Action US Food and Drug Administration requested that Task Force I consider the substitute language.

16 Determining Appropriately Sized Prohibited Areas Associated with Wastewater Treatment Plants

Introduction

Molluscan shellfish are filter feeders and therefore have the ability to concentrate microorganisms from the water column, including human pathogens and toxigenic micro-algae if these organisms are present. Concentrations of microorganisms in the shellfish may be as much as 100 times greater than those found in the water, and if the microorganisms are harmful to humans, illness can result. The correlation between sewage pollution of shellfish waters and illness has been demonstrated many times. Certain shellfish-borne infectious diseases are transmitted via the fecal-oral route, with the cycle beginning with the fecal contamination of the shellfish growing waters.

In the winter of 1924-25, an oyster-borne typhoid outbreak occurred in the United States which caused a large number of illnesses and deaths (Lumsden, et al 1925). In response to this outbreak the National Shellfish Sanitation Program (NSSP) was initiated by the States, the U.S. Public Health Service, and the shellfish industry. Research at the time indicated that typhoid fever would not ordinarily be attributed to shellfish harvested from water in which not more than 50% percent of the one cc (ml) portions of water examined were positive for fecal coliform bacteria (an MPN of approximately 70 per 100 ml), provided that the areas were not subject to direct contamination with small amounts of fresh sewage which would not likely be revealed by routine bacteriological examination. As a result water quality criteria were established, namely;

(1) The area be sufficiently removed from major sources of pollution so that the shellfish are not subjected to fecal contamination in quantities which might be dangerous to public health;

(2) The area be free from pollution by even small quantities of fresh sewage;

(3) Bacteriological examination does not ordinarily show the presence of the coli- aerogenes group of bacteria in one cc dilution of the growing area water.

Once these standards were adopted in the United States in 1925, reliance on these criteria for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Today, fecal and total coliforms are used as an index of the sanitary quality of a growing area and to foretell the possible presence of fecal transmitted bacterial pathogens. The goal of the NSSP remains the same – to ensure the safety of shellfish for human consumption by preventing harvest from contaminated 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 wastewater 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).

(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 & Burkhardt. 2010; Iwamoto et al 2010; Scallan et al. 2011; Batz et al. 2012). NoV genogroups I, II and IV and HAV are human specific 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.
The purpose of this guidance is to provide the scientific basis and recommendations for determining appropriately sized Prohibited Areas (closure zones) based on the minimum criteria established under Section II, Chapter IV. @.03 E(5) of the Model Ordinance (Section E Prohibited Classification).

Classification Requirements for Growing Areas Associated with Waste Water Treatment Plants

The NSSP Model Ordinance (MO) requires that a comprehensive sanitary survey be undertaken prior to the classification of the growing area as Approved, Conditionally Approved, Restricted, or Conditionally Restricted.

The sanitary survey must take careful recognition of any WWTPs as they represent one of the major sources of human sewage pollution. It is preferable that the shellfish growing areas be sited so far away from sewage discharges that the WWTP effluent has no hazardous effect, because there is a direct relationship between the level of WWTP effluent dilution and the level of enteric viruses detected in the shellfish (Goblick et al. 2011).

Delineation of the Prohibited Zone around a Wastewater Treatment Plant

The NSSP MO Section II, Chapter IV. @.03 (2) (b) 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 shall 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 wastewater treatment plant and the bacteriological or viral 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.

There are several important considerations for the shellfish authority to consider when establishing the size of the prohibited zone:

(1) The distance 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.

If the plant is operating outside of the normal parameters it shall be considered to be malfunctioning.

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

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

The following guidelines shall be used when assessing these factors in the dilution analysis for the closure zone:

Volume flow rate: For a minimally sized prohibited zone for Conditionally Approved areas managed in part based on the performance of the WWTP, the maximum monthly average flow at the WWTP recorded in the Monthly Operating Reports (MORs) maintained by the WWTP permitting authority should be used considering at a minimum the most recent two years of flow records. If the maximum monthly average flow at the WWTP from two consecutive years of flow records is within 85 – 100% of the design flow, then the design flow should be used. Thus, these flow values are appropriate when establishing a minimally sized prohibited zone when the WWTP is considered to be operating under normal operating conditions.

Additional information and historical data may be accessed on the U.S. Environmental Protection Agency (EPA) website at:

http://cfpub.epa.gov/dmr/index.cfm. Consistent with the EPA regulations in 40 CFR 122.2, the maximum monthly average flow, which is typically reported in the MOR, is defined as the average ‘‘daily discharges’’ over a calendar month, calculated as the sum of all ‘‘ daily discharges ’’ measured during a calendar month divided by the number of ‘‘daily discharges’’ measured during that month typically expressed in units of million gallons per day (MGD). Thus, the maximum monthly average flow is defined as the highest average monthly flow (MGD) within at a minimum the most recent consecutive two years of flow records. The design flow is defined as the flow (MGD) that the WWTP is designed to discharge and can be expressed as a daily, monthly, or annual discharge. In the design of WWTPs, various flow regimes are considered such as the average flow, maximum flow and peak (instantaneous) flow. However, it is important to note that certain tolerances are allowed under EPA NPDES program and WWTPs are not necessarily expected to meet permit conditions over all flow regimes. Thus, if permit limits are expressed as a monthly average it is considered acceptable for the permitted pollutants to exceed the permit on a short term basis as long as the permit condition (monthly average) is met. It is also important to note that EPA does not have any permit limitations established for the discharge of viruses.

In the context of public health, some of these flow regimes such as when average hourly flows exceed the design flow can be associated with periods of effluent degradation leading to an increase in the viral load in the effluent. Utilizing average hourly flows and comparing against the design flow ensures that the periods when effluent degradation are most likely to occur are adequately identified and assessed. Average hourly flow rates within the most recent two years of records should be evaluated to assess the likelihood that the average hourly flows can exceed the design flow. In the absence of supporting data, the conditional area should be closed when the average hourly flow rates exceed the WWTP design flow due to the potential degradation of the virological quality of treatment. FDA studies have determined that when WWTP average hourly flow rates exceed design flow the virological quality of effluent typically degrades beyond what is considered as normal treatment. Moreover, FDA bioaccumulation studies indicate that shellfish can accumulate significant levels of viral pathogens when exposed in durations of less than one hour. However, a flow level threshold above the design flow could be determined on a case by case basis provided the virological quality of the effluent is assessed. The average hourly flow is defined as the average flow measured over an hour. More detailed flow records are typically maintained and can be accessed through the permitted WWTP.

When conditional management based on WWTP performance is not employed the prohibited zone shall be sufficient in size to dilute the microbial loadings resulting from a WWTP malfunction (such as a sewage bypass or a loss of disinfection) to ensure the Approved area adjacent to the prohibited zone will meet the bacteriological standards for Approved area classification under all conditions including a WWTP malfunction. If the WWTP has no prior history of sewage bypasses then at a minimum a loss of disinfection malfunction shall be considered when sizing the prohibited zone. As many WWTP malfunctions occur from hydraulic overloading as a result of rainfall, snowmelt, storm events or periods of high flow, a maximum average hourly rate shall be considered when determining the size of the prohibited zone. The maximum average hourly flow is defined as the highest average hourly flow recorded within at a minimum) the most recent two consecutive years of flow records.

Location of discharge: The location of the discharge must be determined in order to define the distance from the point of effluent discharge to shellfish growing areas that could be impacted. The distance from shore and the depth of the WWTP outfall also can be used in the dilution analysis of the discharge. The location of discharge includes the location, number, size and orientation of the discharge port(s) on the outfall or its diffuser.

When determining if a WWTP within the watershed or catchment area draining to a shellfish estuary potentially impacts a shellfish growing area, in the absence of a database collected, the NSSP recommends that a worst case raw sewage discharge be assumed. In this circumstance a level of 1.4 x 10^6 FC/100ml assumed for a raw sewage release-requires a 100,000:1 dilution 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. A lower dilution level 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 may 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).

It should also be noted that if shellfish harvesting occurs within the zone of influence from a WWTP then these areas are subject to a WWTP Management Plan as defined in Section II Chapter IV @. 03 C.(2)(a) of the MO. Additionally, if a departure of the normal WWTP function could potentially impact a shellfish growing area then the areas affected should be managed under a conditional management plan as defined in Section II Chapter IV @. 03 C.(2)(a) of the MO.

The minimum size of a prohibited zone for a conditional area under a WWTP management plan should be determined considering both the minimum dilution (1000:1) needed to mitigate the presence of viruses in treated effluent (or a scientifically based alternative approach) as well as the prerequisite notification time to close the conditional area during a WWTP malfunction or period of degraded effluent quality, prior to the conditional area receiving the impact from the WWTP effluent.

Performance of the WWTP: When considering the present and past performance of the WWTP, this review should include information regarding the wastewater collection system, inspection of essential plant components (including any monitoring and alarm systems), events whereby the plant exceeds its design capacity and an evaluation of the disinfection system. The plants past performance should also include a file review of the plant 's Discharge Monitoring Reports, considering at a minimum, the most recent two years of permit records.
When there is evidence that the WWTP exceeds design capacity, consideration should then be given to the frequency of such events and the effect this will have on the plant's ability to reduce the viral load of the effluent .

Consideration should also be given to the frequency of which the WWTP bypasses any stage of treatment or any condition that may degrade the quality of the effluent to determine the potential frequency a conditional growing area may need to close over the course of a year. This assessment will determine the feasibility of operating a conditionally managed area based on WWTP performance.

Bacteriological or viral quality of the effluent: Discharge Monitoring Reports for WWTPs should be examined and periodically monitored to assess the reliability of the disinfection systems. Any samples collected to assess the reliability of the disinfection system should be collected during the period(s) of the year that the State Shellfish Control Authority (SSCA) deems most likely to experience adverse conditions in the treatment or disinfection processes that could affect effluent quality impacting receiving waters.

Results from any bacteriological or viral sampling and analyses must be correlated with WWTP operation and evaluated in terms of the minimum treatment expected when there is a malfunction, overloading or other poor operational condition. However, it is essential to recognize that water samples collected near discharge outfalls are not useful for determining the size of prohibited zones because normal operating conditions in WWTPs can effectively reduce or even eliminate the fecal and total coliforms - the current indicator microorganisms used to assess treatment efficiency. In contrast, many human enteric viruses are not inactivated by functional WWTP systems, hence the need for an adequate dilution zone between the outfall and the shellfish resource.

Decay rate of contaminants: It should be assumed that there is no fecal coliform or viral inactivation in the effluent during possible upset conditions in the WWTP. There are a number of conditions that affect bacterial and viral inactivation, including temperature, exposure to sunlight and sedimentation levels in the water (Burkhardt et al, 2000; Lees, 2002; LaBelle, 1980; Griffen, 2003). Scientists are unsure how long viruses remain viable in the marine environment, but it is likely to be weeks or months (Younger, 2002), and enteroviruses have been found in marine sediments suggesting that these sediments can be a source upon resuspension (Lewis, 1986). Moreover, molluscan shellfish have been found to retain viruses to a greater extent and for much longer periods than they do bacteria (Sobsey et al, 1987; Richards, 1988; Dore and Lees, 1995; Dore et al, 2000; Shieh et al, 2000).

Waste water dispersion and dilution: Dispersion of the effluent refers to the spread, location, and shape of the discharge plume with time as it leaves the WWTP outfall. Dilution of the effluent refers to the amount of receiving water that is entrained within a particular time or distance from the outfall, e.g. the dilution of the effluent within the time or distance it takes to reach the border of the prohibited zone. 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.

In poorly flushed estuaries and coastal embayments there is the potential for WWTP effluent build-up that further reduces the availability of "clean" waters to both dilute contaminant loadings and purge shellfish of contaminants (Goblick et al., 2011).

Time of waste transport to the shellfish harvest site: When there is a WWTP malfunction it is important that adequate systems are in place to officially close the harvest area before the effluent impacts the shellfish. This is a mandatory requirement for conditional management of shellfish harvest areas and all parties must agree in writing on the process steps necessary to close the harvest area after such events. Both time of travel and dilution should be considered when sizing a prohibited zone around a WWTP outfall adjacent to a conditional growing area. The overall sizing of the prohibitive zone should satisfy both a minimum dilution of 1000:1 and also factor in adequate time to respond to a malfunction event. When establishing the time of travel between the WWTP and the classified area, consideration should be given to the worst scenarios which would cause the fastest travel. For example, the peak current flows at or near the outfall during ebb tide and flood tide to determine effluent transport speeds. Current velocity information may need to be generated if such information is not available or adequate for the area of the outfall. Current velocity information can be obtained from hydrographic dye studies, drogue studies, or current meter data conducted in the vicinity of the outfall.

Location of shellfish resources: The best information that is available should be used for locating shellfish resources near the outfall. Subtidal shellfish resources may also be identified in sanitary surveys near WWTP outfalls. Therefore the SSCA must establish closure zones at WWTP outfalls in accordance with the classification requirements of the Model Ordinance.

Classification of Adjacent Waters: If the SSCA's dilution analysis determines that the shellfish water quality standards for approved waters are met at the boundary of the prohibited area during potential upset conditions, the shellfish area adjacent to the prohibited area need not be classified as Conditionally Approved and may be classified as Approved.

Scientific Rationale for 1000:1 Dilution Guidance

Since 1987 FDA has recommended at training courses and other venues the use of a 1000:1 dilution as the minimum level of dilution needed around a WWTP outfall to mitigate the impact of viruses for shellfish harvest areas managed conditionally based on the performance of the WWTP. It has been advised that conditional management based on WWTP performance may not be appropriate for all WWTP' s that are e located within proximity to shellfish harvest areas and recommended only for large, highly efficient WWTPs that are well monitored.. In 1995 this estimated level of necessary dilution was further calculated and explained by FDA using assumptions based on the most relevant scientific literature available at that time (Kohn, et al. 1995; Havelaar et al. 1993; Kapikian et al. 1990; Liu et al. 1966). Since then major advances in the detection and enumeration of NoV in wastewater and shellfish have been made, and advances in fluorometer technologies have enabled more sophisticated hydrographic dye study methods. Using these advances, FDA has conducted dye studies supplemented with the testing of shellfish sentinels for enteric viruses and their surrogates. This has afforded FDA for the first time with a means to directly determine the viral risk posed by WWTP effluent on shellfish resources. During recent years FDA has presented the findings from these studies at regional shellfish meetings, at the biennial ISSC meeting, at international scientific conferences and to international partners engaged in collaborative projects. Results from these studies are referred to herein as part of the scientific basis for the current recommended guidance.

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 the aforementioned technical advances to prospectively assess the 1995 1000:1 dilution estimate recommendation and determine if this level of dilution is appropriate to mitigate the risk of viruses discharged in treated wastewater effluent. From 2008 through 2012 FDA conducted four additional studies (Hampton Roads, Virginia; Yarmouth, Maine; Coos Bay, Oregon; Blaine, Washington). In each of these studies, FDA evaluated male-specific coliphage (MSC) and NoV levels in shellfish together with the dilutions of WWTP effluent. The studies were designed to build a more comprehensive and in- depth understanding of viral impacts posed by WWTPs on shellfish resources.

To date, 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 the use of chlorine, and when they are operating under normal conditions. Results further indicate that in certain instances, such as when WWTPs begin to exceed their design capacity, bypass treatment, or otherwise malfunction, the 1000:1 dilution level may be inadequate and emergency closure procedures should be considered within the conditional area management plan. Under such circumstances, conditional area management plans should ensure there is sufficient time for notification to the State Shellfish Control Authority (SSCA) and for subsequent notifications closing the conditional area to harvesting.

MSC results in shellfish from the 2008-2012 studies were evaluated using 50 PFU/100 g as the threshold level of concern for MSC, since this is the level under the Model Ordinance (Section II, Chapter IV, @.03 A(5)(c)(ii)) 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. For conventional WWTPs operating under normal conditions, there were at least four occasions when dilution levels were between 700:1 and 1000:1 and MSC levels in shellfish exceeded 50 PFU/100g, but there were no occasions in which MSC levels exceeded 50 PFU/100g and dilution was greater than 1000:1. For conventional WWTPs operating under malfunction conditions, such as when flow rates exceeded the design capacity or during a treatment stage bypass, MSC levels in shellfish exceeded 50 PFU/100g in at least 13 instances in which dilution was greater than 1000:1.

When evaluating the NoV results of the 2008 – 2012 studies FDA used a value of 300 RT-PCR units of NoV/100 gram of digestive gland (digestive diverticula) as the threshold. This value was considered significant since at this level shellfish related illnesses have been reported and demonstrated by the analysis of meal remnants.

In examining the results from all the studies, there were no cases in which conventional WWTPs operating under normal conditions produced results greater than 300 NoV particles/100 g of DD in oyster sentinels when dilution levels at the associated sentinel stations were greater than 1000:1. When dilution levels were less than 1000:1, levels of NoV GII greater than 300 NoV particles/100 g of DD were detected, and on one occasion around 8000 NoV particles/100g DD were found.

On three occasions during which WWTPs were operating under malfunction conditions (as previously described), thirteen (13) oyster samples were found with NoV GII levels greater than 300 NoV particles/100 g DD when dilution was close to or greater than 1000:1. These results emphasize the critical need for sufficient notification time, meaning travel time from the WWTP discharge in 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.

In one instance, an unconventional WWTP that used membrane filtration technology rather than conventional treatment with chlorine or UV disinfection was assessed. The levels of NoV GII in shellfish sentinels near this WWTP were greater than 300 NoV particles/100 g of DD, even when dilution levels were greater than 1000:1, and on two occasions when dilution levels exceeded 10,000:1. In seven (7) instances, NoV levels at the plant were greater than 300 NoV particles/100g of DD. MSC levels were similarly high, with all six (6) samples tested having MSC levels greater than 800 PFU/100g, and in one sample greater than 10,000 PFU/100g, even though dilution levels were higher than 1000:1. This analysis demonstrates the need to assess WWTPs with unique treatment systems on a case by case basis, since some may perform better than conventional WWTPs at removing viruses and some may perform significantly worse.

The overall results of FDA's 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. 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 and hence the minimum level of dilution needed to ensure shellfish safety. However, at this time FDA does not have reliable data to justify a recommended minimum dilution less than 1000:1 or to establish any variable dilution thresholds corresponding to and dependent on such factors. It is recognized that these criteria could be determined by a State Shellfish Control Authority (SSCA) on a case by case basis, where factors of WWTP performance, disinfection method, tidal flushing, and seasonal impacts may vary. These and other factors that might influence virus levels in the shellfish can be considered by SSCAs when assessing how best to manage conditional growing areas based on WWTP performance. Using dilution levels lower than 1000:1 or other alternative approaches for managing the viral risk posed by WWTP effluents are cited in Alternate Options section (see below). 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.

Alternate Options

It is expected that the principles of this guidance shall be followed to ensure compliance with the dilution requirements of the Model Ordinance. An alternative minimum waste water dilution threshold value may be appropriate for situations in which highly effective WWTP facilities reduce the viral load of the effluent, or seasonal or geographical factors reduce the risk of viral contamination at the shellfish growing area. Alternative options for calculating the size of the prohibited zone 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 with tertiary treatment operating under optimum design flow conditions. Regardless of the technology employed any proposed alternative minimum threshold 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

It should be noted that any alternate approach would need to consider the time of waste transport to the shellfish harvest site. As described in this guidance in geographic regions with large tidal amplitudes and/or swift tidal currents, the time of waste transport to the shellfish harvest site may be the determining factor in sizing the prohibited zone. However, there may be various strategies that could be employed to address the time of waste transport to the shellfish harvest site. For example, it may be reasonable to expect that if a facility utilized a sufficiently sized containment structure (such as the equivalent to 24-hour holding for the design capacity of the plant) in the event of a malfunction, this would allow the SSCA additional time to react to the event and take any necessary precautions. Regardless of technology or best management practices employed any proposed alternative strategy would need to be validated (i.e. verifying that a containment structure is properly sized and working effectively).

There are likely other alternatives in addressing the potential impact of wastewater on shellfish growing areas and approaches in validating these options. However, the flexibility remains with the SSCA's to determine the appropriate alternate option and validation process that can be verified.

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Public Health Significance:

The public health purpose of this guidance is to provide the scientific basis and recommendations for determining appropriately sized Prohibited Areas (closure zones) around waste water treatment plants (WWTP). Section II, Chapter IV @ .03 (5) currently mandates that a prohibited zone be established, but there is no specific guidance information on how to calculate the size of the prohibited zone to ensure that microbiological pathogens (particularly viruses) from WWTP do not adversely impact the growing area at the time of harvest. It is expected that this guidance will provide all ISSC stakeholders with better information on which to make informed, scientifically based decisions

Cost Information (if available):

Action by 2013 Task Force I

Recommended referral of Proposal 13-118 to an appropriate committee as determined by the Conference Chairman with additional instructions to the ISSC

Executive Office to create a workgroup to meet quarterly and report back to the Conference at the next ISSC meeting.

Action by 2013 General Assembly	Adopted recommendation of Task Force I on Proposal 13-118.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-118.