Proposal No. 2 3 - 1 0 7

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	Robert Rheault
Affiliation	ECSGA
Email	Bob@ecsga.org
Proposal Subject	Data evaluation when the nonpoint sources impacting a growing area are not from a human sewage source
Specific NSSP Guide Reference	Section II. Model Ordinance; Chapter IV Growing Areas; Section @.02 Microbiological Standards F.1.
Text of Proposal/ Requested Action	F. Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources. (1) Exception. (a) If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area. (b) If the Authority has documentation supporting that the nonpoint sources impacting the growing area are not from a human sewage origin they may exclude up to two outlier datapoints from the dataset being evaluated. (2) Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events. (3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (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 fourteen (14) per 100 ml and the estimated 90th percentile shall not 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; or (c) 31 CFU per 100 ml for a MF (mTEC) test. (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by: (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10); (b) Multiplying the standard deviation in (a) by 1.28; (c) Adding the product from (b) to the arithmetic mean; (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number. (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 E. (2). (b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when: (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution; (ii)Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical; (iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area; (iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)(b) (iii) must resume at least six (6) months before an area is reactivated; and (v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard. (c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority: (i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and (ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

Public Health Significance	It is recognized that on occasion water quality may be impacted by non-human sources such as birds. Scientific literature also indicates that the presence of human enteric pathogens in wild birds is overestimated with the use of the coliform indicator (Smith et al. 2021) https://doi.org/10.1111%2Fbrv.12581 If a few aberrant samples can be reliably attributed to birds it is likely that the closure of the harvest area is an unwarranted response
Cost Information	
Research Needs Information (Optional) a. Proposed specific research need/ problem to be addressed	At this time we do not have an estimate of the correlation of human enteric pathogens with coliforms in wild bird waste. Our growing area classification has been entirely built on the correlation between pathogens and coliforms in wastewater. Using the coliform standard to close harvest areas impacted by birds assumes the relationship is similar, when scientific literature indicates that the risk is being overestimated. Research is needed to describe the persistence of bird-sourced pathogens in the marine environment, and how long these pathogens persist in the shellfish if they are taken up by filter feeding bivalves
b. Explain the relationship between proposed research need and program change recommended in the proposal	Research to elucidate the relationship between human enteric pathogens and coliforms will help define the risk of illness associated with consumption of shellfish that may have been impacted by birds. Studies evaluating how these pathogens survive in the marine environment will further inform this relationship. Studies evaluating the purge rates of these pathogens will help growers devise management approaches to ensure potentially impacted product is held away for contaminated sites and is safe for consumption
Action by 2023 Task Force I	Recommended referral of Proposal 23-107 as amended to an appropriate committee as determined by the Conference Chair F. Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources. (7) Exception. (a)If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area. (b) ~~If the Authority has documentation supporting that the nonpoint sources impacting the growing area are not from a human sewage origin they may exclude up to two outlier datapoints from the dataset being evaluated.~~ (8)Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events. (9)Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4). (10) 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 fourteen (14) per 100 ml and the estimated 90th percentile shall not 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; or (c) 31 CFU per 100 ml for a MF (mTEC) test. (11) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by: (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10); (b) Multiplying the standard deviation in (a) by 1.28; (c) Adding the product from (b) to the arithmetic mean; (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number. 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 E. (2). Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when: (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution; (ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical; (iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area; (iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)(b) (iii) must resume at least six (6) months before an area is reactivated; and (v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.

	(d) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority: (i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and (ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1)
Action by 2023 General Assembly	Adopted the recommendations of Task Force I on Proposal 23-107.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-107