Proposal No. 2 3 - 1 2 3

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

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Proposal Subject	**Guidance for calculating the 90th percentile for end-product depurated shellfish**
Specific NSSP Guide Reference	**Section IV Guidance Documents; Chapter II Growing Areas; Section .17 Calculating the 90th percentile for end-product depurated shellfish**
Text of Proposal/ Requested Action	Process verification in depuration is performed continuously to ensure that the microbial contaminant load is being effectively reduced. Two (2) indices of performance, the geometric mean and the ninetieth (90th) percentile have been developed to describe the effectiveness of the depuration process. Critical limits for these parameters have been established empirically by shellfish species. For soft clams (*Mya arenaria*), a geometric mean of fifty (50) and a ninetieth (90th) percentile of 130 have been set. For hard clams, oysters, manila clams and mussels, a geometric mean of twenty (20) and a ninetieth (90th) percentile of seventy (70) have been adopted. Geometric means and ninetieth (90th) percentiles are determined daily or as end- product results become available from the analysis of the most recent ten (10) consecutive harvest lots per species, per restricted harvest area used. If the critical limits for either the geometric mean and/or the ninetieth (90th) percentile are exceeded, the process is considered to be unverified; and, additional sampling requirements must be instituted to ensure effective process control. End-product depurated shellfish samples are analyzed using two (2) different methods of recovery, a pour plate procedure and a single dilution MPN test. Calculation of the ninetieth (90th) percentile for these samples is complicated by the fact that fecal coliforms recovered by the MPN and ETCP methods follow different statistical distributions. To accommodate these differences and maintain a high likelihood for detecting an unacceptable amount of process variability without having to change or alter the formula used requires the use of nonparametric or "distribution free statistics." Using "distribution free statistics," the position of the ninetieth (90th) percentile for end-product depurated shellfish samples is calculated by arraying the fecal coliform count data in ascending order and applying the formula (n + 1)P/100.

	As an example of the use of this formula, the Model Ordinance requires that the ninetieth (90th) percentile of the fecal coliform analytical data be calculated from the most recent ten (10) consecutive harvest lots for each shellfish species depurated from each restricted harvest area. Fecal coliform count data, whether from the ETCP or MPN procedure for these ten (10) lots must be arrayed from the smallest to the largest value using the arithmetic (not logarithmically transformed) count data. Applying the formula, n would be greater than or equal to ten (10) for the ten (10) most recent consecutive harvest lots required by the Model Ordinance. P, the percentile of interest would be ninety (90). Using the minimum sample set of n=10, ~~Multiplying~~ multiplying the formula out gives the position of the ninetieth (90th) percentile in the arrayed data. Performing these calculations, 10 + 1 = 11, 11 x 90 = 990/100 = 9.9. Thus, the ninetieth (90th) percentile for end-product depurated shellfish data when n=10 is the value of the 9.9th sample in the ten (10) sample array. Using ~~the~~ ten (10) samples ~~as required by the Model Ordinance~~, the ninetieth (90th) percentile for end- product depurated shellfish samples would always be the value of the 9.9th sample in the ascending array of the arithmetic count data. To calculate this value from the arrayed data, interpolation between samples nineand ten (10) is necessary. This is best illustrated using several samples. Example 1… Example 2… Example 3… In cases where more than ten samples have been analyzed in the most recent ten consecutive harvest lots for each species depurated or for each harvest area used, the geometric mean and estimated 90th percentiles may be calculated using the methodologies below in examples 4 and 5. Example 4 (attached) Example 5 (attached)
Public Health Significance	Incorrectly calculating the 90th percentile can lead to erroneous decisions that could affect public health. For instance, both the California Dept of Public Health and the FDA mis-calculated the 90th percentile for a data set in which n=36. They insisted, based on the examples given in the NSSP Guide, that the 90th percentile was **always found between the 2 largest numbers** in the data set, even when n is large, which is incorrect.
Cost Information	This clarification to the NSSP Guide, with additional examples, will make it easier to correctly calculate this depuration performance index and should reduce confusion and disagreements, which could save time and money.
Action by 2023 Task Force I	Recommended referral of Proposal 23-123 to an appropriate committee as determined by the Conference Chairperson.

Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-123.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-123