Proposal Number: 01-206

Proposal Subject

Depuration

Specific NSSP Guide Reference NSSP Guide Model Ordinance Chapter XV. Depuration .03 Other Model Ordinance Requirements L. Process Verification (1) (b) and (2)

Text of Proposal/ Requested Action MODIFY Chapter XV.02L (1) and XV.03L (2):

- .03 Other Model Ordinance Requirements
 - L. Process Verification:
 - (1) Perform process verification....

(a

- (b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each restricted harvest area used...
- (2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols: ...

Public Health Significance

By definition, a Depuration Processor (DP) "receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process." All areas submitted to the depuration plant for processing should be included for Process Verification, not just restricted areas as stated in the current section.

Cost Information (if available)

None

Action by 2001 Task Force I Recommended referral of Issue 01-206 to an appropriate committee as determined by the Committee Chairman.

Action by 2001 General Assembly Adopted recommendation of 2001Task Force II.

Action by USFDA

Concurs with Conference action.

Action by 2003 Depuration Wet Storage Committee Recommended no action on Proposal 01-206. Rationale: The proposal is adequately addressed in the Model Ordinance in Chapter XV .02 L (1) and XV.03 L (2).

Action by 2003 Task Force I Recommended referral of Proposal 01-206 to appropriate committee as determined by the Conference Chairman.

Action by 2003 General Assembly Adopted recommendations of 2003 Task Force II.

Action by USFDA

Concurred with Conference Action.

Action by 2005 PHP Committee

Recommended referral of Proposal 01-206 to the appropriate committee as determined by the Conference Chairman.

The discussions of the committee/workgroup should include a review of the Chapter XV requirements for consistency with validation and verification requirements for Vv/Vp reduction and make recommendations to the Post Harvest Processing Committee for

Proposal Number: 01-206

achieving NSSP consistency in validation/verification.

Action by 2005 Task

Recommended adoption of the Post Harvest Processing Committee on

Force II

Proposal 01-206.

Action by 2005 General Assembly Adopted recommendation of 2005 Task Force II.

Action by USFDA Concurred with Conference action.