

<b>Proposal Subject</b>	Depuration
<b>Specific NSSP Guide Reference</b>	NSSP Guide Model Ordinance Chapter XV. Depuration .03 Other Model Ordinance Requirements L. Process Verification (1) (b) and (2)
<b>Text of Proposal/ Requested Action</b>	<p>MODIFY Chapter XV.02L (1) and XV.03L (2):</p> <p>.03 Other Model Ordinance Requirements</p> <p>L. Process Verification:</p> <p>(1) Perform process verification....</p> <p>(a)</p> <p>(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 <del>restricted</del> harvest area used...</p> <p>(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 <del>restricted</del> 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: ...</p>
<b>Public Health Significance</b>	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.
<b>Cost Information (if available)</b>	None
<b>Action by 2001 Task Force I</b>	Recommended referral of Issue 01-206 to an appropriate committee as determined by the Committee Chairman.
<b>Action by 2001 General Assembly</b>	Adopted recommendation of 2001 Task Force II.
<b>Action by USFDA</b>	Concurs with Conference action.
<b>Action by 2003 Depuration Wet Storage Committee</b>	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).
<b>Action by 2003 Task Force I</b>	Recommended referral of Proposal 01-206 to appropriate committee as determined by the Conference Chairman.
<b>Action by 2003 General Assembly</b>	Adopted recommendations of 2003 Task Force II.
<b>Action by USFDA</b>	Concurred with Conference Action.
<b>Action by 2005 PHP Committee</b>	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  $V_v/V_p$  reduction and make recommendations to the Post Harvest Processing Committee for achieving NSSP consistency in validation/verification.

**Action by 2005 Task Force II** Recommended adoption of the Post Harvest Processing Committee on Proposal 01-206.

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

**Action by USFDA** Concurred with Conference action.

**Action by 2007 Post Harvest Processing Committee** Recommended adoption of Proposal 01-206 as amended.

M. Process Verification.

The Dealer shall continually:

(1) **Routine Verification**. Perform process verification on a continuous basis according to the following protocol:

(a) Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample;

(i) from each lot of restricted shellstock to be depurated in the depuration unit.

(ii) **weekly from each lot of approved shellfish to be depurated in the depuration unit.**

(b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90<sup>th</sup> percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.

(c) Compare daily, or as a results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance.

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Limits for Verification of Depuration Plant Performance

Fecal coliforms per 100 grams

Species	Geometric Mean	90 <sup>th</sup> Percentile
Soft Clams ( <i>Mya arenaria</i> )	50	130
Hard Clams ( <i>Mercenaria mercenaria</i> )	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

(d) If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.

(e) For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.

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:...

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| <b>Action by 2007<br/>Task Force II</b>    | Recommended adoption of the Post Harvest Processing Committee recommendation on Proposal 01-206. |
| <b>Action by 2007<br/>General Assembly</b> | Adopted recommendation of 2007 Task Force II.  |
| <b>Action by<br/>USFDA</b>                 | December 20, 2007<br>Concurred with Conference action.   |