

Proposal Subject: Accounting of Shellfish Quantities in Depuration Facilities

Specific NSSP Guide Reference: NSSP Section II Model Ordinance Chapter XV. Depuration

Text of Proposal/ Requested Action: Chapter XV. Depuration
Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this Chapter in regulation.]

- A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:
 - (1) Control shellstock harvesting by special license in accordance with Chapter VIII. @.01 C.;
 - (2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;
 - (3) Approve the design and construction of the depuration facility or activity including subsequent changes;
- B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.
- C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.
- D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.
- E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:
 - (1) Inspection reports and reviews of the plant performance in accordance to Section D. (above);
 - (2) Current Depuration Plant Operations Manual for each dealer (Section.03).; and
 - (3) Precise inventory control and bio-security, before and after the depuration process.
- F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.

Chapter XV. Depuration

Requirements for the Dealer

.03 Other Model Ordinance Requirements

- I. Plant Operations Manual. The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operations Manual shall address:

- (1) Introduction including:
 - (a) Status of document (to create, revise, or update DPOM);
 - (b) Ownership and principal(s) involved with operation of facility;
 - (c) Address and phone number of owners and principles; and
 - (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.
- (2) Description of the facility including:
 - (a) Site plan drawings;
 - (b) Facility layout including detailed schematic of the entire depuration system;
 - (c) Schematic drawing of process;
 - (d) Product flow diagram showing product movement through facility (may be combined with Section 01 B. (3));
 - (e) Statement that construction materials and fabrication will meet the requirements of Section 03 E. (1) and (2); and
 - (f) Schematic of seawater delivery and distribution system.
- (3) Design specifications of depuration unit including:
 - (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
 - (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
 - (c) Shellfish containers construction and material meets Section .04 and Section .08 of this Chapter; and
 - (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.
- (4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);
- (5) Depuration process monitoring including:
 - (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock, depurated shellstock, and growing waters;
 - (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
 - (c) Process water monitoring protocol for physical and chemical parameters; and
 - (d) Data analysis and evaluation.
- (6) Standard Operating Procedure for:
 - (a) Receiving and holding;
 - (b) Washing, culling, and placement of undepurated product in process tanks;
 - (c) Depuration unit operation;
 - (d) Monitoring of depuration unit operation;
 - (e) Removal of depurated product from process tanks;
 - (f) Storage parameters and procedures;
 - (g) Labeling/tagging procedures;
 - (h) Plant cleaning and sanitation; and
 - (i) Data analysis.
 - (j) Recall procedures.

- (7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.
- (a) Shipping and receiving records;
 - (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;
 - (c) Maintenance and Sanitation Log(s);
 - (d) Laboratory records; and
 - (e) Counts of shellfish before and after the depuration process, specifically including the total number, or volume of shellfish. Shellfish sold by the piece after depuration shall be counted by the piece upon landing. If sold by volume, then volume would be recorded at landing.

Public Health Significance: To ensure that all product delivered to the depuration plant is properly placed into the depuration process it is critical that counts and amounts of shellfish are properly counted and volumes properly assessed upon receipt. Harvester allegations of missing or diverted shellfish imply that some product may be diverted from the process.

Cost Information (if available): Since plant operators typically count product after the process, counting at the beginning instead should not impact the cost of the operation.

Action by 2013 Task Force II Recommended no action on substitute Proposal 13-218.

Rationale: There is no public health issue.

Action by 2013 General Assembly Adopted recommendation of 2013 Task Force II on Proposal 03-218.

Action by FDA May 5, 2014 Concurred with Conference action on Proposal 13-218.