

Proposal Subject

Wet Storage

**Specific NSSP
Guide Reference**

NSSP Guide Model Ordinance, Definitions; Chapter I@.02 E; Chapter VII; Chapter VIII@.01 C: Chapter X.05 B, .08 B, and .09 C.

**Text of Proposal/
Requested Action**

Modify current Model Ordinance Wet Storage Definition (106); Chapter 1@.02E; move Wet Storage requirements found under .08 and .09 of Chapter X and incorporate it into Chapter VII (Wet Storage); modify language in Chapter VII by removing, editing, and adding to existing language, as follows:

MODEL ORDINANCE

Definitions.

B. Definition of Terms.

(106) Wet storage means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification, **either loose or** in containers or floats in natural bodies of water, or in tanks containing natural or synthetic seawater **at any permitted land-based activity or facility**.

I. SHELLFISH SANITATION PROGRAM

@.02 Dealer Certification.

E. Interstate Certified Shellfish Shippers List (ICSSL).

(1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. **The Authority shall include any permit designation to be included in the ICSSL.** The notice shall be in the format of FDA Form 3038.

Designations			
Certification		Permit	
SP -	Shucker Packer	PHP -	Post Harvest Processing
RP -	Repacker	AQ -	Aquaculture
SS -	Shellstock Shipper	WS -	Wet Storage
RS -	Reshipper		
DP -	Depuration		

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate **or permit** is:

- (a) Suspended; or
- (b) Revoked.

~~VII. WET STORAGE IN APPROVED AND CONDITIONALLY APPROVED GROWING AREAS~~

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Requirements for the Authority.

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

.01 General.

A. The Authority shall permit all wet storage activities to ensure that all wet storage activities are conducted by certified NSSP shellfish firms.

B. The Authority shall approve and maintain the following records while the wet storage activity continues:

(1) Construction and remodeling plans for any permitted wet storage facility;

(2) Wet storage operational plans;

(3) Wet storage permits; and

(4) Inspection documentation.

C. The Authority shall inspect wet storage activities at the following frequency:

(1) Activities in offshore natural bodies of water at least annually;

(2) Activities at land-based sites with flow-through systems at least every six months; and

(3) Activities at land-based sites with recirculating systems at least quarterly.

D. The Authority shall immediately notify (within 24 hours) all wet storage permit holders affected by a change in growing area classification or status.

E. Shellstock that has been removed from the original harvest area shall not be placed in wet storage more than one time prior to shucking, packing, PHP or consumption.

F. Reshippers shall not engage in wet storage activities.

Requirements for the Dealer.

.01 Source of Shellstock.

A. ~~The dealer~~ **Dealers** shall wet store shellstock harvested only from areas classified as approved, or conditionally approved in the open status, ~~or taken from a certified depuration facility following successful completion of the depuration process.~~

B. Shellstock shall be harvested, identified and shipped to the wet storage ~~operation~~ **activity** in accordance with the requirements of Chapters VIII and IX.

.02 General.

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. **Wet storage shall be deemed a processing activity.**

B. Wet storage of depurated product shall occur only within the facility in which it was depurated. **The shellstock shall:**

(1) Be packed and labeled according to the requirements in Chapter XV; and

(2) Include the dates of wet storage on the labels or tags.

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.

D. While awaiting placement in a wet storage ~~operation~~ **activity**, shellstock shall be protected from physical, chemical or thermal conditions which may compromise shellstock survival, quality or activity during wet storage.

E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

F. ~~For the purpose of certification, each wet storage site or operation shall be evaluated annually. The evaluation shall include an inspection of the near shore storage site and floats, or the wet storage operation.~~

~~G. Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of Chapters VIII, IX and X.~~

F. Shellstock from a wet storage operation activity shall be harvested, handled, identified, processed and shipped according to the requirements of Chapters VIII, IX and X.

G. The harvest date of shellstock that were held in wet storage shall remain the date the shellstock was removed from the original harvest area and this information shall be provided on shellstock tags.

~~H. When the product from wet storage was depurated prior to wet storage, the shellstock shall:~~

- ~~(1) Be packed and labeled according to the requirements in Chapter XV.; and~~
- ~~(2) Include the dates of wet storage on the labels or tags.~~

~~I-H.~~ The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the **original harvest location and** wet storage location, **and include the dates the shellstock were held in wet storage.** The records shall be maintained for at least **a minimum of one year.**

- ~~(1) 90 days from the date of removal of the shellstock from wet storage; and or~~
- ~~(2) 120 days from the date of removal of the shellstock from wet storage where the state of origin labeling is changed under §G.2.~~

I. Unless the dealer is in the Authority's commingling plan under Chapter I.01F different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

.03 Wet Storage Sites in Natural Bodies of Water (Offshore).

A. ~~Nearshore~~ **Natural bodies of waters** used for wet storage ~~in containers and floats~~ shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:

- ~~(1) Subjected to relaying or depuration prior to human consumption; or~~
- ~~(2) Held in the wet storage site until the area is returned to the open status.~~

B. ~~The near shore s~~Site evaluations **of natural bodies of water** shall include:

- ~~(1) The sanitary survey of the near shore storage site, with special consideration of potential intermittent sources of pollution;~~
- ~~(2) The location of near shore storage sites and/or floats; and~~
- ~~(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock.; and~~
- (4) A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.**

~~C. Different lots of shellfish shall not be commingled during wet storage. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.~~

[Sections below are moved from Chapter X to Chapter VII]

~~.09~~ **.04 Wet Storage in Artificial Bodies of Water (Land-based).**

A. General.

(1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII.01 and .02.

(2) For the purpose of permitting, each wet storage site or ~~operation~~ **activity** shall be evaluated ~~annually~~ **in accordance with @.01.B**. The evaluation shall include **a review of the operation's plan and operating procedures for conducting an onshore land-based wet storage activity as submitted by the dealer.**

(3) Prior to commencing construction, all plans for construction or remodeling of ~~onshore~~ wet storage facilities ~~or operations~~ shall be reviewed and authorized by the Authority.

(4) The wet storage facility ~~or operation~~ evaluation shall include a review of:

- (a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
- (b) Any species specific physiological factors that may affect design criteria; and
- (c) The plan giving the design of the ~~onshore~~ **land-based wet** storage facility, source and quantity of **process** water to be used for wet storage, and details of any **process** water treatment **(disinfection)** system.

B. Operation Specifications.

(1) General. Each ~~onshore~~ **land-based** wet storage ~~operation~~ **activity** shall meet the following design, construction, and operating requirements.

- (a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
- (b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
 - (i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and
 - (ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
- (c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
- (d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(2) Buildings. When a building is used for the wet storage ~~operation~~ **activity**:

- (a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and
- (b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.

(3) Outdoor Tank Operation. When the wet storage ~~operation~~ **activity** is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

- (a) Prevent entry of birds, animals or vermin; and
- (b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. ~~Water Supply~~ **Wet Storage Source Water**

(1) General.

(a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification **and water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water.**

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI.02 **(with the exception of the salt content in salt water wells).**

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the source water supply shall be maintained for at least 2 years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) and do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected process water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water and follow the protocol of the Decision Tree (IV. Guidance Documents Chapter III.06, or shall have no viable bacteria as measured weekly by the absence of turbidity (growth) in 100 ml of the disinfected process water cultured in a nonselective bacterial culture broth medium listed in Standard Methods for the Examination of Water and Wastewater, APHA, for 24 hours at 35°C.

(g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group or any positive result for viable bacteria, daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected process water to show positive results for the coliform group or the presence of viable bacteria is eliminated, the effectiveness of the correction shall be ~~shown~~ verified on the first operating day following correction through the ~~immediate~~ collection, ~~within~~ over a 24 hour period, of a set of three samples of disinfected process water ~~and one sample of the source water prior to disinfection.~~

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.

(j) The disinfection unit(s) for the process water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(2) Continuous Flow-through System.

(a) If the system is of continuous flow-through design, water from a growing area classified as:

(i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or

(ii) Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status may be used if the source water is continuously subjected to disinfection and it is sampled and analyzed daily following disinfection.

(b) When a source classified as Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status is used, a study shall be required to demonstrate that the disinfection system ~~will~~ can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:

(i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;

- (ii) Include one sample daily for five consecutive days from the source water prior to disinfection;
- (iii) Use NSSP recognized methods to analyze the samples ~~to~~ if determining ~~determine~~ coliform levels;
- (iv) Require all samples of disinfected water to be negative for the coliform group; and
- (v) Be repeated if any sample of disinfected process water during the study is positive for the coliform group or viable bacteria.

(c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group or free of detectable viable bacteria.

(d) When other than approved water is located between the intake of a flow-through wet storage system and the land-based facility then the Authority may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that ~~the disinfection system~~ for the recirculating system ~~will~~ can consistently produce water that tests negative for the coliform group or viable bacteria under normal operating conditions. The study shall meet the requirements in §C.(2)(b) above.

(b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group or viable bacteria.

(c) When make-up water of more than 10 percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected ~~within~~ over a 24 hour period to reaffirm the ability of the system to produce process water free from the coliform group or viable bacteria.

(d) When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. ~~Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage,~~ Any deviation to this requirement is subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I@.01F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage process water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

VIII. CONTROL OF SHELLFISH HARVESTING.

@.01 Control of Shellstock Growing Areas.

C. Licensing of Harvesting.

(3) A license to harvest shall not allow a harvester to engage in shellstock packing or engage in independent wet storage activities as defined in this Ordinance unless the harvester is a ~~shellstock shipper or packs for a dealer.~~ certified shellfish dealer and has a Wet Storage Permit issued by the Authority.

X. GENERAL REQUIREMENTS FOR DEALERS

.05 Shellstock Identification.

B. Tags.

(1) The dealers' tags shall:

- (a) Be durable, waterproof and sanctioned by the Authority prior to use; and
- (b) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:

- (a) The dealer's name and address;
- (b) The dealer's certification number as assigned by the Authority
- (c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;
- (d) The date of harvest; or if depurated, the date of depuration processing;
- (e) If depurated, the depuration cycle number or lot number;
- (f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number)-
- (g) When the shellstock has been ~~transported across state lines and~~ placed in wet storage in a dealer's operation, the statement: "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";
- (h) The type and quantity of shellstock; and
- (i) The following statement in bold capitalized type on each tag:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."
- (j) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock:
"RETAILERS, INFORM YOUR CUSTOMERS"
"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

.08 Shipping Documents and Records.

B. Transaction and Shipping Records.

- (1) Each dealer shall have a business address at which transaction records are maintained.
- (2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
 - (a) Document that the shellfish are from a source authorized under this Ordinance;
 - (b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
 - (c) Permit a lot (or commingled lots as per Chapter I.@.01.F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.

~~.09 Wet Storage in Artificial Bodies of Water. [Delete Section .09 in its entirety from Chapter X.]~~

**Public Health
Significance**

This proposal would take all of the Wet Storage requirements currently found under Chapter X .09 and incorporate them into Chapter VII. This movement places all of the wet storage requirements under a single chapter of the Model Ordinance. The rationale for this reorganization is to simplify the utility of the Model Ordinance when determining which criteria would be applicable for wet storage activities. Under the Model Ordinance's Definition of Terms for "Wet Storage" (106) recommends adding the word "loose" and adding "permitted land-based activity or facility." By adding the word "loose" the definition includes a wet storage activity that does occur, however, the current definition only refers to wet storage in containers or floats. Adding "at any land-based activity or facility" simply differentiates this form of wet storage from off-shore wet storage. In Chapter I the words, "Authority shall include any permit designations" including "Wet Storage (WS)" in the ICSSL were added to ensure that particular certified dealers are permitted to conduct wet storage activity only after being evaluated for meeting the specific Model Ordinance guidelines. Wet storage is intended only to enable dealers to maintain shellstock temporarily in a healthy, viable, safe condition until sold.

The word, "activity" was substituted for "operation" in most places throughout the proposed changes, since wet storage qualifies as a post-harvest processing activity.

Existing paragraph F under Ch VII .02 (General) was removed and new paragraph F was added. This existing F requires annual inspection and specifies what must be inspected. These requirements have been moved to @.01 "Requirements for the Authority" since the Authority is responsible for inspections. Also the inspection frequency is now broken down to include various inspection frequencies based on the type of wet storage activity and the variables and risk associated with each. New paragraph F keeps some original language from the existing MO paragraph G regarding compliance for the wet storage operation with Chapters VII, IX and X.

New paragraph G states unambiguously that the original date of harvest and the original harvest area remain described on tags for shellstock that have been wet stored. Wet storage is nothing more than a means to temporarily store and in minor ways perhaps process shellfish, not create a new identity.

New paragraph I reinforces the provisions of new paragraph G with new words added. It is proposed with the addition of language to ensure that wet storage operators will keep complete and accurate records to enable each lot of shellfish stored to be traced to the original harvest location. In addition, the record retention required of the wet storage operator is extended from the original language to 1 year, to be consistent with other record keeping requirements in the current MO, for HACCP, and to reflect possible further raw, frozen storage before consumption.

All references to Near-shore were changed to Off-Shore to differentiate the Land-based wet storage activity from Off-shore wet storage activity, for clarification purposes.

Current .04 C Water Supply was renamed "Wet Storage Source Water."

In .04 C (1) , C (2), and C (3), an alternative to fecal coliform testing has been added, one which provides equivalent or even better assurance of disinfection and should reduce costs to operators. Suitable disinfection of process water can be readily measured as the absence of viable bacteria in 100 ml.

Section 2 "Continuous Flow-through System" the Proposal recommends addition of a new paragraph (d) which allows the Authority to require the wet storage operator periodic verification of the piping system integrity if said piping system runs through water which is classified as Other than Approved. This would provide additional assurance that the failure of the piping has not allowed contaminated water to enter a wet storage system.

In Chapter VIII under Section @.01 “Control of Shellstock Growing Areas” C. “Licensing of Harvesting” the proposal recommends adding to the original language that the licensed harvester cannot engage in independent wet storage activities unless they have a Wet Storage Permit issued by the Authority. This is consistent with the requirements of the MO regarding harvester’s limitations. The purpose for this change was to provide traceability to the original harvest location regardless if the product was harvested in-state or transported from another state’s harvest waters.

In Chapter X under Section .08 “Shipping Documents and Records” “B” “Transaction and Shipping Records” (c) a requirement was added for shellstock taken from wet storage that provides records to allow a lot of shellstock to be traced to the date and location of wet storage activity. This will provide consistency with the other requirements relating to this Section of the MO regarding record keeping.

**Cost Information
(if available):**

Passage of this issue would add no additional costs to a State’s program.
There are no additional expenses to industry either, since new requirements for the wet storage facility or laboratory analyses are not made.

**Action by 2005 Task
Force II**

Recommended referral of Proposal 05-205 to appropriate Committee as determined by the Conference Chairman with a recommendation by Task Force II that a workgroup under the appropriate Committee be established to address this proposal before the 2007 Biennial Meeting.

**Action by 2005
General Assembly**

Adopted recommendation of 2005 Task Force II.

Action by USFDA

Concurred with Conference action.