

Additional Guidance - Section IV Guidance Documents
[Chapter II.06 Shellstock Relay](#)

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.

The Authority shall assure that:

- A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;
- B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;
- C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by the coliform group of indicator organisms in the water, or poisonous or deleterious substances that may be present in shellstock to occur; and
- D. If shellstock are relayed in containers:
 - (1) The containers are:
 - (a) Designed and constructed so that they allow free flow of water to the shellstock; and
 - (b) Located so as to assure the contaminant reduction required in §C.; and
 - (2) The shellstock are washed and culled prior to placement in the containers.

@.02 Contaminant Reduction.

- A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.
- B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay activity;
 - (1) The bacteriological quality of each shellfish species, is the same bacteriological quality as that of the same species already present in the approved or conditionally approved area; or
 - (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels.
- C. The authority may waive the requirements for a contaminant reduction study if:
 - (1) Only microbial contaminants need to be reduced; and

- (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV@.02.G and Chapter IV@.02H; and
- (3) The treatment period exceeds 60 days.
- D. The time period shall be at least 14 consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.
- E. When container relaying is used and the Authority allows a treatment time of less than 14 days, the Authority shall require more intensive sampling including:
 - (1) Product sampling before and after relay, and
 - (2) Monitoring of critical environmental parameters such as temperature and salinity.
- F. The Authority shall establish the time period during the year when relaying may be conducted.

@.03 Licenses to Relay Shellstock or to Harvest Shellstock for Delivery to a Low Acid Canned Food Processing Facility.

- A. The Authority shall require that each harvester that relays or harvests shellstock for delivery to a low acid canned food processing facility from growing areas in the conditionally approved (in the closed status), restricted or conditionally restricted classification possesses a valid harvester or relay license.
- B. The license conditions shall not be transferable.
- C. A license shall be valid only when issued for:
 - (1) A specific relay or harvest activity; and
 - (2) Not more than 365 days.
- D. The license conditions shall include:
 - (1) The source, destination, and species to be relayed or harvested for low acid canned food processing;
 - (2) The relayed or harvested for low acid canned food processing shellstock deposition method;
 - (3) The method used to maintain adequate separation between different lots of shellfish;
 - (4) A requirement for the licensee to keep records which:
 - (a) Specify the dates on which the shellstock is harvested, deposited for treatment and harvested again, or delivered to a low acid canned food processing facility;
 - (b) Identify the buyer and quantity of shellstock harvested for relaying or delivery to a low acid canned food processing facility; and
 - (c) Are submitted to the Authority at a specified frequency, if required by the Authority, or made available to the Authority upon request; and
 - (5) A provision for additional information at the discretion of the Authority.
- E. If the relay harvester or harvester for low acid canned food processing fails to comply with the conditions of the license, the Authority shall revoke the license.

@.04 Management of Relaying Shellstock or the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities.

- A. The Authority shall be authorized and equipped to enforce the State's procedures for relay and low acid canned food processing. The Authority shall develop and maintain an effective program to control the harvest, transport, replanting, and security of the shellstock until the end of the complete relay activity to prevent shellstock from being illegally diverted to direct marketing.

- B. In the event that the control of relaying or harvesting for low acid canning activities is shared among two or more agencies, the Authority shall develop written operating procedures for joint use among the agencies. These procedures shall provide for the achievement of all requirements specified in this Chapter, and shall be reviewed annually and updated as necessary.
- C. If shellstock from growing areas classified as conditionally approved or restricted are to be relayed or harvested for low acid canned food processing across State boundaries, a memorandum of understanding outlining the procedures to be used shall be developed between the appropriate Authorities in each State.
- D. If a growing area in the conditionally approved classification meets the criteria for the restricted classification when the growing area is in the closed status, the Authority may permit shellstock to be harvested for relaying or low acid canned food processing during the period the area is in its closed status, provided that these activities are addressed in the management plan for the growing area classified as conditionally approved, and all other conditions of this Chapter are met.
- E. Locations designated to receive relayed shellstock within growing areas which are classified as approved or conditionally approved shall:
 - (1) Be placed in the closed status until the period of treatment is complete and the Authority returns the area to the open status; and
 - (2) Be marked so that these areas are easily identified by harvesters transporting the relayed shellstock and by the Authority. These areas shall:
 - (a) Be marked prior to the placing of any shellstock;
 - (b) Remain marked until the Authority reopens the area and gives written permission to harvest shellstock; and
 - (c) Be adequately separated from the shellstock in adjacent waters to prevent cross-contamination and commingling.

Requirement for Harvesters.

.01 Harvester License Required.

- A. Any person who wants to relay shellstock or to harvest shellstock from a growing area classified as conditionally approved, restricted, or conditionally restricted shall make application to the Authority for a valid license to relay or to harvest shellstock.
- B. No person shall relay shellstock or shall harvest shellstock for low acid canned food processing without a valid harvester license from the Authority.