

Proposal Subject: Guidelines for Primary Certified Shellfish Processors on Using Controls for Irradiation of Containers of Molluscan Shellfish Pre-labeled with Vibrio Reduction Language

Specific NSSP Guide Reference: Section IV. Guidance Documents
Chapter III. Harvesting, Handling, Processing, and Distribution

Text of Proposal/ Requested Action Add New Section .09

.09 Irradiation Pre-labeling Guidance

This document provides guidance to primary certified shellfish processors involved in transferring pre-labeled shellfish to be processed at irradiation post-harvest process (PHP) facilities.

Vibrios are highly sensitive to ionizing radiation. The National Shellfish Sanitation Program (NSSP) recognizes Vibrio reduction processes such as irradiation and provides general requirements for dealers using them. For irradiation the following guidelines provide additional detail:

- All shellfish irradiation facilities and shellfish processors using an irradiation facility to PHP shellfish must be recognized by their State Shellfish Control Authority (SSCA) as a certified PHP facility and comply with NSSP Model Ordinance Chapter XVI.

- Irradiation facilities must utilize a process that has been validated in accordance with the NSSP to achieve a reduction of *V.v.* and/or *V.p.* to less than 30 MPN/g. The process shall not irradiate shellfish to an absorbed dose of greater than 5.5 kGy, as provided by 21 CFR § 179.26. While the size of the container of shellfish does not affect the ability of the process to provide the proper dose of irradiation to all shellfish in a process batch, once a process has been validated it is essential that all containers be of uniform size with the same number of containers on each pallet. This is also important for purposes of product tracking and control. Each processor wishing to use an irradiation facility that has already been recognized and validated in accordance with the NSSP does not have to revalidate the irradiation process being used. Further, if a NSSP recognized irradiation facility conducts verification sample testing, processors using that facility to PHP shellfish may use those verification sample results to fulfill their NSSP verification requirements.

- The shellfish processor and the irradiation facility must have implemented a Hazard Analysis Critical Control Point (HACCP) plan approved by the respective SSCAs for the PHP process that ensures the target pathogen(s) in shellfish are consistently reduced to levels recognized as safe in the NSSP Model Ordinance.

- Once the irradiation process is completed containers of irradiated shellfish should be segregated from other shellfish or seafood products.

Under 21 CFR § 179.26(c), molluscan shellfish that are irradiated must bear a specific logo and a statement specifying that the shellfish have been treated by irradiation or treated with radiation. However, PHP irradiation facilities that irradiate shellfish may not have the capability to also label the shellfish as irradiated; such facilities can only irradiate the shellfish, not label them. As such, the primary processor may pre-label the pallets of shellfish as irradiated and may also provide a statement detailing Vibrio reduction.

For dealers who ship shellfish to an irradiation facility in containers that have been pre-labeled as irradiated with vibrio reduction information the following guidelines provide additional detail:

- A signed agreement should be in place between the irradiation facility and the primary certified shellfish dealer specifying the post office addresses of each party and outlining the specifications needed to ensure that the pre-labeled containers of shellfish do, in fact, undergo the validated irradiation process set forth within the agreement.
- Both the primary shellfish dealer and the irradiation facility must each have an implemented HACCP plan to ensure that shellfish pre-labeled as irradiated undergo the validated irradiation process set forth in the agreement.
- The agreement should provide for transport of the shellfish in sealed trucks and the transport should be secured with a tamperproof seal at the primary certified dealer and a record should be made of the seal number.
- The agreement should also establish that the oyster shellstock is washed, sorted, and placed into pre-labeled containers by the primary certified shellfish dealer.
- The agreement should specify how to palletize pre-packaged and pre-labeled oyster containers.
- Pallets of oyster containers shall be clearly labeled with the words “TO BE IRRADIATED.”
- The number of pre-labeled containers should be documented in a HACCP record and in an additional record to be provided to the operator at the irradiation facility. This transport should be limited to pallets of shellfish to be irradiated and no other seafood or shellfish products.
- When the transport arrives, the irradiation facility operator may remove the seal, record the number of containers, verify the number of containers in the transport matches the record provided by the primary certified dealer and then record the number of containers in the irradiation facility’s HACCP record.
- The irradiation facility operator shall record all other required HACCP receiving critical limit information in HACCP records.
- Irradiated shellfish shall be placed in cooler storage or on transports maintained at the appropriate temperature (cooler maintained at 45 degrees and transport pre-chilled to 45 degrees).
- Irradiated shellfish shall be segregated from other seafood or shellfish products.
- The irradiation facility shall also have implemented a HACCP plan that includes the critical control points for receiving, the irradiation process, and refrigerated storage.

**Public Health
Significance:**

Vibrio bacteria are predominately found in estuarine environments and naturally present in most shellfish. Most cases of disease attributed to Vibrio species are

associated with the consumption of raw molluscan shellfish, particularly raw oysters and hard clams. *Vibrio*-related sicknesses can cause severe illness, including mortality. The most common *Vibrio* species found in shellfish are *Vibrio vulnificus* (*V.v.*) and *Vibrio parahaemolyticus* (*V.p.*). *V.v.* is associated with 95 percent of all seafood-related deaths in the United States. Thus, *Vibrio* species in uncooked molluscan shellfish provide a significant public health risk which may be minimized by enabling industry to streamline this process for irradiation PHP.

**Cost Information
(if available):**

**Action by 2013
Task Force II**

Recommended adoption of Proposal 13-226 as submitted.

**Action by 2013
General Assembly**

Adopted recommendation of 2013 Task Force II on Proposal 13-226.

**Action by FDA
May 5, 2014**

Concurred with Conference action on Proposal 13-226.