

<b>Proposal Subject</b>	Maintenance of Identify of Origin on all Raw Molluscan Shellfish
<b>Specific NSSP Guide Reference</b>	Chapter X. General Requirements for Dealers .06 Shucked Shellfish Labeling
<b>Text of Proposal/ Requested Action</b>	<p>(4) At a minimum the dealer shall label each individual package containing <del>fresh or frozen shucked</del> <u>raw</u> shellfish meat, <b><u>whether in the shell or removed there from, including fresh, frozen or that processed with any other procedure that has not been determined to be equivalent to cooking,</u></b> in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.</p> <p><b><u>(5) The dealer shall assure that:</u></b></p> <p>(a) <b><u>The shucker-packer’s or repacker’s certification number is on the label of each package of fresh or frozen shellfish</u></b> and the most precise identification of the harvest location as is practicable, including the initials of the state and the Authority’s designation of the growing area, by indexing, administrative or geographic designation, is unambiguously indicated on the label of each package of raw shellfish, including post-harvest processed shellstock, shucked meats, and whole or parts of frozen shellfish, whether in the shell or removed there from.</p>

**Public Health Significance**

Unlike the requirements for maintenance and unambiguous declaration of origin on containers of all raw/live shellstock that is processed, distributed and offered for sale in retail outlets and in food service establishments, there persists an exception that permits omission of a label designating the true harvest area for certain raw shellfish products. There is no specific requirement for declaration of the state and growing/harvest area location that would apply to shucked and other raw shellfish that have been subjected to some process that would not be considered biochemically (microbiologically) equivalent to cooking. In lieu of maintenance of harvest area origin, these products may be packed and distributed under the label designation and certification identifier of the entity that shucked, processed or repacked shellfish that it has received from a primary or secondary source in another geographic area. This is clearly a circumvention of the original intent of maintenance of identity of origin for raw shellfish products.

The “rationale” for such an exception has been based on the assumption that all shucked shellfish are cooked prior to consumption. It is quite evident that this is certainly not the case; many restaurants present to the table pre-shucked oysters or previously frozen oysters in the “half-shell mode”; some dealer’s actually supply empty shells to restaurant buyers to facilitate such procedures.

Another argument is based on the declared impracticality and added burden that maintenance of identity of origin on the final product would impose on the processor. The perception - and consequent justification that the maintenance and declaration of origin on the final packaging of processed shellfish is impracticable and excessively burdensome is certainly not sustainable in light of the currently available technologies (vd. information on costs).

A third objection derives from the assumption that the origin of the product can eventually be traced via the records that the final processor/shipper is required to maintain. This argument is difficult to justify in light of the widely recognized utility of maintenance of true origin on all other raw shellfish – a long-standing policy of the NSSP. Indeed, when instances of shellfish related disease outbreaks occur, it is quite helpful to both local and regional health authorities to have immediate access to the least ambiguous information pertaining to the true origin of the suspect shellfish lots. There is a high probability of an erroneous origin for the suspect product being established and disseminated by local health authorities unfamiliar with the details of the NSSP requirements. This confusion of origin promulgated and fostered via the uncritical communication media, can result in misdirected and ineffective responses by both the consumer community and well-intentioned agencies involved in food

safety issues acting on defective information. Such dispersion of effort is counterproductive in such situations.

Though not directly a public health issue, it is propitious that a reputable industry, considering the litigious nature of current society, would make every effort to avoid the eventual accusations of “consumer fraud”, which could be fabricated by so-called consumer interest groups that would not hesitate to use the obfuscation of product identity as a pretext in their hysteria-driven anti-industry campaigns.

The reputable retailer and thoughtful consumer have a legitimate expectation of truth in product identity. Maintenance of identity of origin has been a fundamental concept of the shellfish sanitation program since its inception; remedying the exception to this key component of the program is long overdue.

**Cost Information  
(if available)**

For small shucking and processing operations (up to a few hundred containers per day), label making machines are available for less than 300 dollars; there will be less than one hour of labor per process cycle to apply and prepare marked containers; this operation can be integrated with other container handling procedures associated with product packing. For larger operations that require practical labeling of large numbers of containers, a stand-alone, industrial quality ink-jet printer system can be obtained for less than 10,000 dollars, which can be amortized at a reasonable annual rate over an expected service life of 15 years. Most printers can be configured to apply identifying labels without operator attendance. Daily setup and routine maintenance is minimal.

**Action by 2007  
Task Force II**

Recommended no action on Proposal 07-210. Rationale – Concerns regarding traceability and record keeping are already being addressed.

**Action by 2007  
General Assembly**

Adopted recommendation of 2007 Task Force II.

**Action by  
USFDA**

December 20, 2007  
Concurred with Conference action.