<b>Proposal for Consid</b>	
	Sanitation Conference Harvesting/Handling/Distribution
2011 Biennial Meet	
Name of	U.S. Food and Drug Administration (USFDA)
Submitter:	Interstate Shellfish Sanitation Conference Executive Office(ISSC)
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Subject:	Certification Requirements for Retail Distribution Centers
Specific NSSP	Section II. Model Ordinance Chapter X. General Requirements for Dealers
Guide Reference:	
Key Words:	Retail; Chain; Warehouse; Distribution
Text of Proposal/	.04 Certification Requirements.
<b>Requested Action:</b>	A. General.
	(1) Except as specified in (4) below, Nno person shall act as a dealer prior
	to obtaining certification.
	(2) Any person who wants to be a dealer shall:
	(a) Make application to the Authority for certification;
	(b) Have and implement a HACCP Plan, and have a program of
	sanitation monitoring and record keeping in compliance with 21
	CFR 123 as it appears in the <i>Federal Register</i> of December 18,
	1995, except for the requirement for harvester identification on a dealer's tag.
	(3) Each dealer shall have a business address at which inspections of
	facilities, activities, or equipment can be conducted.
	(4) A Retailer that operates a Distribution Center that receives and
	distributes molluscan shellfish is not required to obtain certification as
	a shellfish dealer if:
	(a) the Distribution Center ships shellfish only to retail outlets that are
	owned and operated by the same company that owns and operates
	the Distribution Center;
	(b) the Distribution Center receives the shellfish from a source listed
	on the ICSSL and distributes the product to the retail stores in the
	original containers in which it was received; and
	(c) from the time the shellfish is received at the distribution center to
	the time of sale or service to the consumer, the shellfish is
	maintained under the ownership and control of the company that
	owns and operates the Distribution Center and the retail stores.

## **Public Health Significance:**

FDA considers retail food stores that receive molluscan shellfish from company-owned Distribution Centers that operate in the manner described above to be in compliance with 3-201.15 of the FDA Food Code, even if those Distribution Centers are not listed in the ICSSL. State and local regulatory authorities that license food stores may wish to take additional steps to be assured that the Distribution Centers can be considered an acceptable source, such as verifying that the Distribution Center maintains the shellfish as 45 deg F or below during storage and transit to the retail store.

This exception to II.X.04 applies regardless of whether one or more of the retail stores to which the product is shipped is located in a different State from where the distribution center is located and regardless of whether the distribution center and/or the stores are located in a State that has a program for certifying shellfish dealers.

If all three conditions listed in the proposed X.04.A. (4) are not met, then a Distribution Center that receives and ships shellfish in interstate commerce should seek certification and listing on the ICSSL.

Food safety concerns related to this policy should be minimal since no breakdown or repacking of shellfish is taking place and safe distribution and receiving is the responsibility of a single retail company and their own stores. Also the ability to effective conduct a product traceback should not be compromised by this because ownership of the product isn't being transferred if the stores and Distribution Center are part of same company.

## **Cost Information** (if available):