Seafood HACCP Guidance

What is Seafood HACCP?
Hazard Analysis Critical Control Point (HACCP) is a systematic approach to identify and control biological, physical and chemical hazards related to the procurement, storage, handling, production and distribution that can cause a food product to be unsafe. An effective HACCP system will eliminate or reduce the risks to an acceptable level. A HACCP system is required to be implemented for all wholesale processors and distributors of seafood.

Examples of seafood:
• Fish (freshwater, saltwater, farmed and wild)
• Turtle, frog, alligator and shark
• Roe and caviar
• Shrimp, crab and lobster
• Anchovy paste, lobster ravioli, salmon croquette, smoked fish
• Sea urchin, sea cucumber and abalone
• Eel, squid and octopus
• Fish oil dietary supplements
• Molluscan Shellfish (mussels, clams, oysters and scallops)
• Prepackaged canned tuna, crab, sardines, mackerel and fish sauce

What regulations apply to Seafood HACCP?
All seafood manufacturers must adhere to Good Manufacturing Practices (21 CFR 110), Seafood HACCP (21 CFR 123) and all applicable state regulations.

Are there exemptions from the Seafood HACCP regulation?
Retail establishments, fishing vessels, transporters who do not process seafood, and practices on the harvest vessel to prepare seafood solely for storage on-board are not required to operate under a HACCP system. Hazards associated with the harvest and transportation of seafood are required to be evaluated by the receiver.

What type of training is needed?
At a minimum, standardized training or equivalent job experience is required to perform HACCP plan development, re-assessment and modification. Additionally, record review of Critical Control Point monitoring, corrective actions, and process control instrument calibration must be conducted by a trained or otherwise qualified individual (21 CFR 123.10). To meet the training requirement, the Seafood HAACP Alliance Basic HACCP training course or both Segment 1 (online course) and Segment 2 (live course) must be successfully completed; other courses may be acceptable. More information can be obtained from the Association of Food and Drug Officials (AFDO).

Steps to complete before wholesaling seafood:
• Find a commercial processing facility that meets the Food Establishment Minimum Construction Standards.
• Receive a training certificate in HACCP principles for fish and fishery products or be able to demonstrate an equivalent knowledge.
• Complete your registration with FDA to be in compliance with the Bioterrorism Act.
• Perform a hazard analysis on EACH fish and fishery product in which you wholesale.
• Prepare a HACCP Plan for each fish and fishery product in which you identified as a hazard.
• Prepare to document monitoring of the eight key areas of sanitation that apply to your operation.
• Contact the Division of Food Safety to request your initial inspection at 1-800-HELP FLA.
What are the required prerequisites?
Sanitation is a prerequisite program that is necessary for the effective implementation of HACCP. The regulation does not require written sanitation control procedures. However, the regulation requires written records documenting the results of monitoring of sanitary conditions and practices in the facility to correct any deficiencies that were noted during monitoring (21 CFR 123.11). Monitoring must be conducted for the key areas of sanitation that apply to your operation:

- Safety of water
- Condition and cleanliness of food contact surfaces
- Prevention of cross contamination
- Maintenance of hand washing, hand sanitizing and toilet facilities
- Protection of food and food packaging from adulterants
- Proper labeling, storage and use of toxic compounds
- Exclusion of pests
- Control of employee health conditions

What should you expect during a Seafood HACCP inspection?
Your facility and equipment will be thoroughly inspected to assess sanitation practices and your implementation of Good Manufacturing Practices and Seafood HACCP. The inspector will observe processing activities in order to identify any potential hazards and evaluate the controls that you have implemented. The Fish and Fishery Products Hazards and Controls Guidance is a resource the inspector uses to assess these hazards and controls. A comprehensive review of the required records is necessary to determine compliance with the regulations and verify the effectiveness of your HACCP system. At the conclusion, an inspection report will be issued and an opportunity for questions and clarification provided.

Frequently asked questions
FDA: Questions and Answers for Guidance to Implement of a HACCP System in Seafood