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MANDATORY HACCP INSPECTION FOR SEAFOOD & AQUACULTURED PRODUCTS

On December 18, 1995 the long anticipated regulation for a new method of inspection for food safety in the seafood and aquaculture industry was adopted by the U. S. Food & Drug Administration (FDA). The new system is named "HACCP" for the proven concept of Hazard Analysis and Critical Control Point programs designed to prevent and control food safety problems. Justification for the program was based on continuing concerns for seafood-borne illnesses, public expectations, industry requests, and market trends in both domestic and international settings. Regulatory response considered HACCP as the most cost-effective way to ensure seafood safety. HACCP relies on more industry self-regulation through "preventative maintenance" with regulatory oversight. FDA has allowed two years for industry compliance by December 1997.

WHO MUST COMPLY ?

- ◆ **Processors**- firms either in the United States or in a foreign country, engaged in handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding fish and fishery products.
- ◆ **Importers** - U.S. owners or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner at time of entry. Foreign processors will be influenced indirectly through requirements for U.S. importers to ensure their suppliers comply with HACCP programs equivalent to that for domestic processors.
- ◆ **Products Involved** - fresh or saltwater fish, crustaceans, all mollusks, alligators, frogs, aquatic turtles, jellyfish, sea cucumbers, sea urchins, other aquatic animal life except mammals and birds, and the roe from these animals, if intended for human consumption. A fishery product includes fish or shellfish as the characterizing ingredient.
- **Exempted** - harvesting or transporting the involved products without otherwise processing, retail operations and practices such as heading, eviscerating, or freezing intended solely to prepare [involved products] for holding on board a harvest vessel. Note, harvesters and transporters can be influenced indirectly through a processors' product and shipping specifications as relate to their HACCP Plans.

WHAT IS REQUIRED ?

- ◆ **Prerequisite Programs** (before installing HACCP)

HACCP Plans will be in addition to the existing requirements for:
 - *Current Good Manufacturing Practices (GMP's: 21 CFR 110)
 - * Sanitary Standard Operating Procedures (SSOP)
 - * related regulations to prevent economic fraud
- ◆ **Written HACCP Plans** based a hazard analysis for food safety for each location where the involved products are "processed" and for each kind of involved product(s). Contents of the written HACCP Plan include:
 1. List of the food safety hazards "reasonably likely" to occur.
 2. List of the critical control points (CCP's).
 3. List of the critical limits that must be met at each CCP.
 4. Monitoring procedures for each CCP.*
 5. Any pre-determined corrective action plans*
 6. List of the verification procedures to assure the HACCP Plan is adequate.*
 7. Record keeping system to document the monitoring of the CCP' s.*

*includes dating and signature requirements
- ◆ **Sanitation Control Records for the SSOP**
Each "processor" shall maintain sanitation control records that, at a minimum, document the monitoring and corrections for the conditions and practices during processing with sufficient frequency to ensure conformance with sanitation standard operating procedures (SSOP's) and good manufacturing practices (GMP's).

REGULATORY AUTHORITIES

- ◆ **FDA** issued the final rule for HACCP inspection for fish and fishery products. They are responsible for the enforcement in accordance with the Federal Food, Drug and Cosmetic Act. In the absence of an appropriate HACCP program can be considered adulterated and subject to regulatory actions and penalties.
- ◆ **State regulatory authorities** will be adopting the federal mandate and assisting with enforcement as done for similar food regulations applicable to food processing and importing. In Florida, the primary regulatory authorities for seafood and aquacultured product processing are the Department of Environmental Protection (for blue crabs and mollusks) and the Department of Agriculture & Consumer Services (for other aquatic foods).
- ◆ **National Marine Fisheries Service (NMFS)** will continue to maintain their voluntary fee-for-services inspection program which includes an experienced HACCP element. Their HACCP services are not mandatory.

TRAINING REQUIREMENTS

According to FDA's new HACCP regulation, at a minimum, the following functions 'shall' be performed by an individual(s) trained in the application of HACCP principles to fish and fishery product processing:

- * Developing the HACCP Plan
- * Reassessing and adjusting the HACCP Plan in accordance with corrective actions and verifications
- * Performing record reviews

Training should be equivalent to that available through a standardized curriculum recognized as adequate by the U.S. FDA. Currently this curriculum is the 2½ day training program developed by the national "Seafood HACCP Alliance". This program will be offered through the regional affiliates of the Association of Food & Drug Officials (AFDO) utilizing established trainers from academic, industry and regulatory programs about the nation. Job experience and other training formats can qualify an individual to perform the required functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

SEAFOOD HACCP ALLIANCE

The National Sea Grant College Program has funded a two-year project to develop the Seafood HACCP Alliance for education and training services. The initial Alliance consists of members of the three principle federal agencies; FDA, USDA and NMFS, various State agencies through the Association of Food & Drug Officials regional affiliates, the Interstate Shellfish Sanitation Conference, and various Sea Grant College programs from coastal states. The Alliance has developed and pilot-tested a HACCP Core Curriculum to accompany their Compendium of Methods and FDA's new Fishery Products Hazard Guide. These materials will be available to support training programs after July 4, 1996.

Dan Smyly, Florida Department of Agriculture & Consumer Services (Tallahassee), is the Chairman of the Alliance's Organizational Committee helping to arrange the training programs, and Steve Otwell, FL Sea Grant College Program at the University of Florida is the National Coordinator for the Alliance. These Florida employees can be reached for additional information on Alliance activities.

This HACCP brief is a condensed version based on the final rule, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products". issued in the federal register (Vol. 60 No. 242) on December 18, 1995. The actual rule should be referenced for accuracy and more detail. The brief was compiled 2/7/96 by:

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