

MANDATORY HACCP INSPECTION for SEAFOOD & AQUACULTURE IMPORTERS

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.

HOW DOES HACCP INFLUENCE IMPORTERS?

While importers have always been responsible for compliance with FDA regulations that prevent the entry and commerce of adulterated foods, previous practice depended solely on regulatory surveillance. The new mandatory HACCP regulations include requirements for importers to become more proactive in ensuring the safety of the imported seafoods and aquacultured products. In addition to traditional import surveillance and periodic inspections, FDA will now require certain HACCP controls.

WHO MUST COMPLY ?

- ◆ **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.
- ◆ **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.
- ◆ **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 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 the 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 BY IMPORTERS?

If the importer also preforms some processing in accordance with the aforementioned definition, a HACCP program must be considered to address this activity as required for all domestic and foreign processors. If the importer is not involved in processing, they are not required to have a HACCP program for the products in question, but they must help ensure foreign processor compliance. Foreign processors must maintain HACCP programs as required for U.S. processors. The burden of compliance and/or proof is shared by the U.S. importer. In this situation, the new mandatory HACCP regulation specifies two options for importer compliance:

1. **Import involved products from a country with an established and recognized "MOU" (Memorandum of Understanding) with the United States.** If an appropriate MOU exists, the importer does not need to take any further action. FDA has established internal protocol for developing MOUs and will be committed to negotiating as many MOUs as possible. It will ultimately be the importer's responsibility to keep apprised of any changes in the status of HACCP related MOUs.
2. **In the absence of MOUs, the importer must have and implement "verification" procedures. The FDA regulation specifies that these procedures must include two parts**
 - a. **Product specifications** that ensure the involved products are not injurious to health and have been processed under sanitary conditions.
 - b. **Affirmative steps or options** that ensure the involved products are produced under controls that meet the requirements of the HACCP regulations for processors. Options include:
 - i) Obtain the foreign processors' HACCP and sanitation records as related to the specific lot of imported fish or fishery products;
 - ii) Obtain a continuing or lot-by-lot certificate from an appropriate government inspection authority or competent third party;
 - iii) Regularly inspecting the foreign processors' facilities;
 - iv) Maintain on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the processor ensuring performance;
 - v) Periodically testing the imported products, and maintaining on file a copy, in English, of a written guarantee from the processor;
 - vi) Other appropriate verification measures that provide an equivalent level of assurance of compliance.

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 the involved products 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 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(s) need not be an employee of the processor.

FDA agrees that the need for training is the same for foreign processors as it is for domestic processors. FDA has no objection to HACCP training being performed in the country of origin by "an official agency" or other entity, as long as the course of instruction is at least equivalent to that provided by the standardized course to be provided by the "Seafood HACCP Alliance".

Unless involved in processing, **importers are not required to obtain specific HACCP training**, but this training can help in understanding and developing the necessary "verification" activities for their foreign suppliers/processors.

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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