HACCP GUIDE FOR THE AQUACULTURE INDUSTRY

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INTRODUCTION

The U.S. Food and Drug Administration published a final regulation on December 18, 1995 that requires all seafood processors in the U.S. and foreign countries that export seafood products to the U.S. to apply the food safety control system called HACCP (Hazard Analysis and Critical Control Point) to their operations by December 18, 1997.

Seafood businesses required to comply with this regulation include: traditional processors who manufacture, preserve, prepare, shuck, eviscerate, freeze or change seafood products into different market forms as well as wholesale, distribution or other firms that handle, store, hold, pack, or label seafood or engage in dockside unloading. Harvesters, retail establishments, and transportation companies were exempted from this regulation. Specific requirements were also included for seafood importers, smoked fish, and bivalve molluscan shellfish.

The FDA regulation is based on and incorporates the principles of the preventive food safety control system called HACCP. While aquaculture facilities are generally not covered by these regulations, you may engage in certain practices that are covered. This fact sheet will help in determining whether your business needs a HACCP plan, and answer frequently asked questions about HACCP as it relates to aquaculture.

WHAT IS HACCP?

HACCP is a preventative system of food safety controls. A HACCP system is designed to: identify the significant hazards associated with your products or operations, and establish procedures to monitor your products and operations to ensure that these hazards are controlled.

HACCP Means:

- Hazard
- Analysis
- &
- Critical
- Control
- Point

An easy way to say HACCP is "hassup"

A HACCP system requires the application of seven principles to identify and control food safety hazards: (1) hazard analysis, (2) critical control point identification, (3) establishment of critical limits, (4) monitoring procedures, (5) corrective actions, (6) verification procedures, and (7) record keeping. HACCP can not be effective unless
all seven principles in the system are used together. Leaving one or more of these components out of a HACCP plan negates the benefits of such a plan.

IS HACCP NEW AND WHY IS IT IMPORTANT?

HACCP is not a new concept. It was first used in the 1960's to produce the safest food for the space program. While seafood was the first food commodity to have a mandatory HACCP requirement, meat and poultry plants are now also using this system of process controls. Application of the HACCP system is now being considered for other foods such as fruits, fruit juices and vegetables. By prioritizing and controlling potential hazards in food production, the aquaculture industry can better assure consumers of their products' safety. The HACCP system is recognized by scientific and food safety authorities as the most effective approach available for producing safe food.

WHAT'S IN A HACCP PLAN?

Each firm who meets the FDA definition of a processor is required to conduct a hazard analysis to identify any significant food safety hazards that are reasonably likely to occur for their unique operation. The hazard analysis process requires that firms consider the potential hazards associated with each species of fish or shellfish that they handle or process as well as the potential food safety hazards associated with each step of their operation.

When significant food safety hazards are identified in this analysis, a HACCP plan is developed to prevent, eliminate or reduce the hazard to an acceptable level at critical steps in the operation. The HACCP plan identifies each significant hazard and the Critical Control Points (CCPs) in the operation where the hazard will be controlled. At each of these CCPs, critical limits are established along with monitoring and a record keeping system to demonstrate that the identified hazards have been controlled. Potential food safety problems that need to be considered are biological hazards, like bacteria; chemical hazards, like toxins; and physical hazards, such as metal or glass. Corrective actions are developed to ensure that procedures are in place to correct problems and prevent unsafe products from entering the marketplace when established critical limits are not met. Periodic procedures are also required to verify that the HACCP plan is working effectively. In addition to the HACCP controls, seafood firms are also required to monitor and keep records of their monitoring results and corrective actions for eight areas of sanitation identified in the FDA regulation (see FDA-CFSAN web site for more details).

HACCP AND AQUACULTURE-DO I NEED A PLAN?

Are Aquaculture Producers Defined as Processors Under The Seafood HAACP Regulation?

The answer to this question depends on the type of activities that you conduct. The following questions and answers represent responses to this and other questions provided by FDA in letters to USDA and in the January 1999 edition of the Questions and Answers which is published periodically to help firms determine their responsibilities under the FDA seafood HACCP regulation.

Question: Is an aquaculture producer a "processor" under the seafood HACCP regulation?
Answer: No, aquaculture producers are exempt from coverage (by the FDA regulation). Treatment with carbon dioxide, bleeding, washing, and icing of otherwise unprocessed fish by the aquaculture producer is an integral part of the process of harvesting and getting the fish to market, and is therefore not considered to be processing. However, heading, gutting, or packaging of fish (e.g. retail or wholesale packages or cartons) performed by the aquaculture producer is considered processing, and would subject the producer to coverage under the regulation.

Question: Does a pay lake operator or fish farm that sells and "custom processes" fish from the farm for direct consumption by the end user need a HACCP plan?
Answer: When a producer custom processes fish directly for the consumer, that part of the operation
would be considered a retail establishment and therefore exempt from the seafood HACCP regulations. However, the producer must abide by the state and local laws governing retail food establishments. Furthermore, such an establishment is exempt even if it is transported across a state line. The transportation can be by the customer, a delivery service offered by the producer, or a delivery service provided by common carriers.

**Question:** Does holding live lobsters in a pound constitute "holding" as defined in the seafood HACCP regulation?

**Answer:** Yes, the practice of holding live lobsters until they are marketed is a form of processing as defined by the regulation. Consequently lobster pounds are subject to the sanitation and HACCP requirements of the regulation. At a minimum, safety concerns to consider in the development of a HACCP plan for these operations include water quality and use of animal drugs.

**Question:** Are businesses that buy live fish from producers and transport them, often through interstate commerce, alive to retail establishments that directly market these live fish to their customers exempt from HACCP regulations?

**Answer:** Yes, since they are transporting fish without otherwise engaging in processing. However, under the FDA Food Code, which many state and local regulators have adopted, the retail establishments that receive the live fish have to address any safety hazards which could occur.

**Question:** What activities of a molluscan shellfish harvester are exempt from the requirements of the seafood HACCP regulation?

**Answer:** A person is exempt from all provisions of the HACCP regulation if they engage in the activity of harvesting molluscan shellfish without otherwise processing the shellfish. The following harvesting activities are not considered to be "processing":

- Temporarily holding shellstock in bulk, or in containers, in a part of the same natural shellfish growing waters where harvested, where such holding is an integral part of the operation of getting the harvested product to market
- Placing shellstock in containers as they are harvested
- Placing shellfish shipping tags on containers of shellstock
- Sorting or washing shellstock in the harvest area
- Transporting by the harvester of shellstock in a boat or truck to a processing facility

**Question:** Are molluscan shellfish wet storage facilities covered by the seafood HACCP regulation?

**Answer:** Yes, if the shellfish are harvested from the growing water and moved to another body of water (natural or artificial) in which they are then held awaiting marketing, the wet storage would be considered processing, as defined by the regulation, in that it constitutes "holding" or "storage." However, if, for example, aquacultured shellfish are harvested and then temporarily resuspended in a container in the same area during the remainder of the harvesting operation, the temporary storage would not be considered "holding", but rather a necessary part of the harvesting operation.

**Question:** When does temporary storage by a culturist become "processing" as defined in the seafood HACCP regulation?

**Answer:** Holding or storage by a culturist is not covered by the regulation when temporary storage is a necessary component of harvesting and getting the product to market. However, such holding is covered if it is performed while a marketing decision is being made.

The following activity is considered temporary storage and is not covered by the regulation:

- A culturist holds his harvest until he can deliver it to market, or until it can be picked up for delivery to market.

The following activities constitute "holding" and are covered by the regulation:

- A shellfish farmer harvests oysters and stores them for several days until she has enough to sell.
- A clam farmer stores his and others’ clams in his cooler, until they are picked up by a truck or sold elsewhere.
- A wholesale dealer buys trout from a number of farmers and holds them for pick up by a common carrier.
Another consideration relative to whether or not the products produced by an aquaculture firm are covered by the seafood HACCP regulation relates to whether or not the products are in *interstate* commerce which is the type of commerce for which federal agencies like FDA have jurisdiction. Interstate commerce is defined in the Food Drug and Cosmetic Act section 201(b) as "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body. A product is in interstate commerce if a component originated from another state, territory, or country, or if the finished product itself moves to another state, territory, or country."

The FDA has responded to specific questions related to interstate commerce by firms or groups seeking further clarification. The following Questions and Answers from the Third Issue (January 1999 Revision) of the FDA Q&A guide for HACCP Implementation may help aquaculture firms further evaluate their status in relation to interstate commerce.

**Question:** If a firm sells their product intrastate to another processor, such as a warehouse, which distributes interstate, is the original firm covered (by the FDA regulation)?

**Answer:** Yes, firms that sell their product intrastate to another processor with knowledge that the product will then be introduced into interstate commerce, or with good reason to believe that the product will be introduced into interstate commerce, are subject to the requirements of the seafood HACCP regulation.

**Question:** If a firm receives raw materials from outside the state and distributes the finished seafood product inside the state, is the firm subject to the (HACCP) provisions for this product?

**Answer:** Yes, this scenario constitutes interstate commerce, and subjects the product to the provisions of the (HACCP) regulation.

**Question:** Are domestic firms that produce seafood for export considered to be processors under the FDA regulation?

**Answer:** Yes, exportation is a form of "interstate commerce" and therefore those who process seafood products for export meet the definition of processor and must comply with the seafood HACCP regulation. However, the Import/Export section (Section 801(e)(l)) of the Federal Food Drug and Cosmetic Act exempts export products, including food, from the adulteration provisions of the Act if they meet the following criteria:

- accords to specifications of the foreign purchaser,
- is not in conflict with the laws of the country to which it is intended for export,
- is labeled on the outside of the shipping package that it is intended for export, and
- is not sold or offered for sale in domestic commerce.

Thus, seafood products to be exported that meet these criteria would be exempt from the seafood HACCP regulation provisions.

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**Can I write my own plan?**

Yes, but the FDA Seafood HACCP regulation also included a requirement that certain activities including development of the HACCP plan, reviewing records, and reassessing or modifying the HACCP plan be conducted by a *trained individual* or someone who is otherwise qualified by obtaining knowledge equivalent to that provided by training *through job experience*. A national initiative called the Seafood HACCP Alliance was developed with funding support from the National Sea Grant College Program to develop and deliver a seafood HACCP training program. The Seafood HACCP Alliance was a collaborative effort of Sea Grant University Seafood Specialists, Food and Drug Administration, United States Department of Agriculture, National Marine Fisheries Service, the Interstate Shellfish Sanitation Conference, the Association of Food and Drug Officials, and industry trade organizations such as the National Fisheries Institute and the National Food Processors Association. A standardized three day training course was developed, and recognized by FDA as meeting the regulation's training requirement and as the standardized curriculum by which other training...
programs could be evaluated. By the end of 1999, over 10,000 individuals completed a seafood HACCP training course conducted in the U.S. Attending an Alliance training course or an equivalent training course is one way to ensure that the FDA training requirement has been met. What is most important, however, is that all significant food safety hazards are identified and an effective HACCP plan has been developed and implemented to control these hazards.

**SEAFOOD SAFETY HAZARDS THAT MAY BE ASSOCIATED WITH WILD AND CULTURED FISH AND SHELLFISH PRODUCTS**

While the HACCP regulation does not specifically apply to culturists, they need to be aware of the types of food safety hazards that may affect their product. Aquaculture producers may need to consider several specific food safety hazards associated with where the product is grown or held.

<table>
<thead>
<tr>
<th>The FDA has identified hazards associated with near shore coastal areas:</th>
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<td><strong>Shellfish</strong>: Pathogens from the harvest area, Natural toxins, environmental chemical contaminants and pesticides.</td>
</tr>
<tr>
<td><strong>Finfish</strong>: Natural toxins and environmental chemical contaminants and pesticides.</td>
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<td>Aquaculture producers may also need to include controls for any drugs that are used in their operation.</td>
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**Understand the Hazards**

There are several different types of food safety hazards. Each is different and therefore require different control mechanisms. To ensure product safety you need to understand the hazards and how they can be controlled. Even if you don’t need a plan you should understand the hazards; who you sell to may need this information for their plan. What each hazard is, how to control those hazards and how to monitor your process for such hazards follows.

**Environmental chemical contaminants and pesticides** in fish and shellfish cultured in waters exposed to varying amounts of industrial chemicals, pesticides, and toxic elements pose a potential human health hazard. These contaminants may accumulate in "fish or shellfish tissues" at levels that can cause illnesses associated with long term exposure. Concern for these contaminants primarily focuses on fish and shellfish cultured and harvested from fresh waters, estuaries, and near shore coastal waters, rather than the open ocean. Pesticides used near aquaculture operations may also contaminate fish.

**Natural toxins** from the harvest area can contaminate fish and shellfish and cause consumer illness. These toxins are produced by species of naturally occurring marine algae, and they can accumulate in fish when they feed on the algae or on other fish that have feed on the algae. There are 5 recognized fish poisoning syndromes in the U.S.: paralytic shellfish poisoning, neurotoxic shellfish poisoning, diarrhetic shellfish poisoning, amnesic shellfish poisoning and ciguatera fish poisoning. Paralytic shellfish poisoning or PSP is generally associated with molluscan shellfish from the northeast and northwest regions of the U.S. The PSP toxin has also been reported in the viscera of mackerel, dungeness crabs, tanner crabs, and red rock crabs. Neurotoxic shellfish poisoning or NSP in the U.S. is generally associated with molluscan shellfish from the Gulf of Mexico and Southern Atlantic coast. Diarrhetic shellfish poisoning or DSP is generally associated with molluscan shellfish in other parts of the world but no cases have been documented in the U.S. Amnesic shellfish poisoning or ASP is associated with molluscan shellfish from the northeast and northwest coasts of North America and has been recently identified in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies from the west coast of the U.S. Marine shellfish toxins are generally not a problem in scallops if only the adductor muscle is consumed. Ciguatera fish toxin has been associated with certain fish species such as jacks, barracuda, king mackerel, and large groupers and snappers from tropical and subtropical parts of the world.
Unregulated drug use in aquacultured fish and holding pounds also poses a potential human health hazard. These substances may be carcinogenic, allergenic, and/or may cause antibiotic resistance in humans. To control this hazard in food animals, all drugs, whether for direct medication or for addition to feed, must be approved by FDA. The reasons for use of animal drugs in aquaculture include the need to: 1) treat and prevent disease; 2) control parasites; 3) affect reproduction and growth 4) tranquilization. Relatively few drugs have been approved for aquaculture. As a result, aquaculture growers may use unapproved drugs, general-purpose chemicals that are not labeled for drug use, and approved drugs in a manner that deviates from the labeled instructions. Labels of approved drugs list mandatory withdrawal times, where applicable. These withdrawal times must be observed to ensure that the edible tissue is safe when it is offered for sale. Tissue residue tolerances have been established for some drugs; FDA randomly tests salmon tissue for drug residue during transport.

Controlling Chemical Contaminants, Natural Toxin Hazards and Aquaculture Drugs.

Federal tolerances and action levels are established for some of the most toxic and persistent contaminants that are found in fish. States often use these levels to decide whether to issue consumption advisories or to close waters for harvesting of all or certain species of fish. In the case of molluscan shellfish, Shellfish Control Authorities consider the degree of chemical contamination or the presence of natural toxins as part of their classification of harvesting waters. Where PSP or ASP have become a problem in finfish or crustaceans, states have generally closed or restricted appropriate fisheries. In addition, the removal and destruction of the viscera from finfish will eliminate the hazard of natural toxins.

Environmental chemical contaminants and natural toxins are primarily controlled at the receiving step when it is reasonably likely to expect that unsafe levels of chemical contaminants could be associated with certain species harvested from a particular area. The historical occurrence of environmental chemical contaminants at levels above tolerance or action levels or of natural toxins in a particular geographic area can be used to make this determination. Since this hazard is either present in the product at unsafe levels when it is harvested or not, it can be fully controlled by the primary processor or first receiver of the product from the producer. The first receiver could control this hazard by checking the harvest area for reports to determine whether there is a history of chemical contamination or health advisories. Secondary handlers or processors of seafood products other than molluscan shellfish (clams, oysters, and mussels) do not need to identify this as a significant hazard in their HACCP plan. Cooking, heating, or other processing techniques cannot reliably eliminate these hazards.

The first receiver of the product from the aquaculture firm also controls the hazard of aquaculture drugs at the receiving step. FDA suggests that acceptable preventive measures for this hazard that can be utilized by the first receiver of the product include:

- Pre-harvest visits to the aquaculture firm to review drug usage
- Supplier's lot-by-lot certification of proper drug usage coupled with appropriate verification
- Review of drug usage records at receipt of product
- Drug residue testing
- Evidence that the producer operates under a 3rd party audited Quality Assurance Program for aquaculture drug use.

HACCP PLAN CRITICAL LIMITS AND MONITORING REQUIREMENTS

If any of the three hazards are determined to be critical you have to set limits and monitor for them.

First receivers of products other than molluscan shellfish will be likely to ask producers to report to them information about the harvest location and its status (e.g. is it open or closed to commercial
fishing) to meet their critical limit of not accepting any products from an area closed to fishing by federal, state, or local authorities. Some buyers may select the option of asking for a certificate that indicates that the fish were not harvested from waters where contaminant levels in the fish are likely to exceed established tolerance, action, or guidance levels. For molluscan shellfish, all buyers will check as before that the product is properly tagged and that the tag contains the required information to verify that product was harvested from approved harvesting waters where chemical contaminants or natural toxins are not likely to be a significant hazard.

The hazard of aquaculture drugs is also controlled at the receiving step by the first receiver of the product from the aquaculture firm. FDA suggests that acceptable control measures for this hazard that can be utilized by the first receiver of the product should ensure that animal drugs are used on fish only if the drugs have been:

- Approved by FDA and used in accordance with proper withdrawal times and other labeled conditions; Or
- Approved by FDA and used in an extra label manner under a veterinarian's supervision in accordance with FDA regulations and guidelines; Or
- Listed on the FDA "low regulatory priority aquaculture drug list; Or
- Permitted by FDA for use in food fish under the conditions of an INAD (Investigational New Animal Drug) as evidenced by a lot-by-lot written certificate from the grower.


VERIFICATION

In a HACCP system periodic verification is required. The purpose of such verification is to ensure that the critical limits and monitoring procedures used to control the identified hazards are valid. Verification is performed initially for each new source of product then at least once a year thereafter. For example, since the environment and our knowledge of it changes, one could check with the local health department if health advisories were issued for a given growing area once a year. Receivers of farmed salmon could verify that the producer is not using any drugs that aren't approved by FDA; this can be further checked by independent testing.

HACCP RESOURCES:

HACCP Training and Guidance Manuals


Fish and Fisheries Products Hazards and Controls Guide. U.S. Food and Drug Administration, 2nd Edition, January 1998. Available from NC Sea Grant at the address above for $15. Also may be available from local FDA or Sea Grant offices. Can also be accessed via the Internet at the FDA Website: http://vm.cfsan.fda.gov or the Seafood Network Information Center at the University of California at Davis Website: http://www-seafood.ucdavis.edu This manual provides FDA guidance on seafood safety hazards that should be evaluated in the Hazard Analysis process and guidance on appropriate elements of a HACCP plan including critical control points, critical limits, monitoring, corrective action, record keeping, and verification procedures for each hazard.

Internet Resources:

FDA Center for Food Safety and Applied Nutrition: http://vm.cfsan.fda.gov

The Center for Food Safety and Applied Nutrition's home page is full of resources, including a HACCP link that contains the full regulation along with other helpful information for those looking for a place to start. Note that the Seafood and Regulatory Fish Encyclopedia (including images) is here as well.
Seafood Network Information Center: http://www-seafood.ucdavis.edu

The Seafood Network Information Center, based at the University of California/Davis is a good general resource site. Generic HACCP plans, HACCP forms and training resources are available.

The National Food Safety Database (search HACCP): http://www.foodsafety.org/index.htm

Primarily funded by the United States Department of Agriculture, The National Food Safety Database is a multi-state/multi-agency effort that is working towards a sustainable system of national food safety databases. This site has links to consumer and industry-related food safety resources, including HACCP.

Aquaculture Network Information Center: http://aquanic.org

The Aquaculture Network Information Center maintained at Purdue University is a great general-purpose site for aquaculture information. HACCP information is not linked from the home page, but can be found under "Internet Sites."

The Delaware Aquaculture Resource Center: http://darc.cms.udel.edu

Maintained at the University of Delaware, the Delaware Aquaculture Resource Center is an archive of information about aquaculture in Delaware and the Mid-Atlantic region. HACCP resources can be found under "Other Links" and "Education/Training."

National Sea Grant Depository- HACCP Digital Library: http://nsgd.gso.uri.edu/haccp.htm

A digital library of Sea Grant-funded HACCP publications. Instructions are provided for accessing publications not yet digitized.

Maryland Sea Grant Extension- HACCP Page: http://www.mdsg.umd.edu/Extension/HACCP

This site has links to general HACCP resources as well as information specific to Maryland, Virginia and North Carolina.

Processor HACCP Manuals and Publications


Educational Videos/Slide Sets


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