SRAC Publication No. 4900

Southern Regional Aquaculture Center

February 2004

The HACCP Seafood Program and Aquaculture

Russell Miget[1]

Regulations governing the safe processing and importing of fish* and fishery products were enacted by the U.S. Food and Drug Administration (USFDA) in December, 1997. The regulations take a preventive approach to food safety. Biological, chemical and physical hazards are identified, then process controls are established to minimize the risk of food-borne illness. From this approach comes the acronym HACCP, which stands for Hazard Analysis and Critical Control Point.

The National Seafood HACCP Alliance, in cooperation with the USFDA, has developed a standardized curriculum and offers a 2 1/2-day training course. Two reference documents, the training guide and the controls guide, are provided. See the References section for information on obtaining these documents and participating in the training.

The controls guide lists more than 250 species of finfish and some 80 species of invertebrates, each with somewhat different species-related hazards (e.g., histamine, ciguatera fish poisoning, parasites, etc.). The guide also describes 28 process related hazards (e.g., ready-to-eat products; vacuum and modified atmosphere packaging; smoked, dried, raw products, etc.)

This publication describes the procedure for developing a HACCP plan and aspects of HACCP unique to aquaculture products.

HACCP and food safety

It is important to note that the biological, chemical and physical hazards which are to be controlled in a HACCP program are related to food safety and not food quality. While it is important from a business standpoint to produce high quality seafood products, and while the measures taken to produce safe products no doubt contribute to quality, the two parameters should be kept separate when developing a HACCP plan. For example, insects, filth, hair, and even spoilage by non-pathogenic microorganisms are undesirable in food and would certainly make it low quality. However, because these are not directly related to food safety, they can be controlled by following Good Manufacturing Practices (GMPs) such as plant sanitation and personal hygiene. These require much less stringent record keeping than a process directly related to food safety, such as the cooking time and temperature necessary to kill pathogenic bacteria in ready-to-eat products.

Remember, HACCP is about food safety and its purpose is to prevent unsafe products from entering the market. Previous inspection systems checked for economic fraud as well as food quality and safety, and relied on end-product testing and the subsequent recall of products found to be unsafe.

History

The concept of HACCP as a food safety system started in 1959 when NASA asked the Pillsbury Company to develop a system for ensuring that food prepared for astronauts was virtually 100 percent safe. The traditional end-product testing would not satisfy this requirement, because so much product would have to be tested to satisfy statistical requirements that little would be left for the astronauts. This dilemma actually raised a couple of questions about food processing in general, namely: 1) Because companies at the time did not carry out extensive end-product testing, just how safe was our food supply? and 2) What might the industry do, using new technology, to approach the 100 percent safe level for all consumers, not just astronauts?

[1]Texas A&M University

*including all forms of aquatic life (i.e., finfish, invertebrates, alligators, frogs, etc.)

The researchers concluded that the best approach to food safety would be to develop a preventive system which would require control over the raw materials, processes, environment, personnel, storage, and distribution early in the system. Combined with adequate record keeping, such a system could virtually eliminate the need for *routine* end-product testing. Such testing could be relegated to *verification* that a particular process is operating correctly.

The HACCP system was introduced in 1971 during the National Food Protection Conference. In 1985 the National Academy of Sciences recommended that the HACCP system be adopted by all food regulatory agencies and that it become mandatory for all food processors. Since that time, HACCP has been adopted for seafood, red meat, pork, poultry, fresh fruits and vegetables, and other food processes.

HACCP has been endorsed by most of the countries to which aquaculture producers would be shipping, namely, the European Union, Canada, Australia, New Zealand and Japan, as well as by the United Nations through its Codex Alimentarius program.

Seafood processors must keep in mind that HACCP *does not replace* GMPs or guard against fraudulent practices. Inspectors will continue to evaluate plants for proper sanitation, employee hygiene, non-safety food standards, and even economic fraud (e.g., species mislabeling, incorrect size counts, etc).

HACCP and aquaculture

The USFDA regulations governing seafood processing are found in Title 21, Part 123 of the Code of Federal Regulations issued in December, 1997, which is titled "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products." As the title indicates, importers and processors, both domestic and foreign, must comply.

An **importer** is defined as either the U.S. owner or the U.S. agent of the foreign owner at the time of the product's entry into the U. S. This person is responsible for ensuring that goods entering the U.S. are in compliance with all laws affecting importation. Every importer shall either 1) obtain fish or fishery products from a country that has an active Memorandum of Understanding (MOU) or similar agreement with the USFDA that documents the equivalency or the compliance of that country's inspection system with the U.S. system, or 2) have written verification to ensure that products were processed in accordance with the requirements of this regulation.

A **processor** is defined as any person engaged in commercial, custom or institutional processing of fish or fishery products either in the U.S. or in a foreign country. **Processing** means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding fish or fishery products. Eviscerating or heading on board a harvest vessel—not a factory trawler—with the sole intent to hold, but not process, the catch is exempt from these regulations. However, evisceration / heading carried out at an aquaculture facility before delivery to a processing plant must comply with these regulations.

While aquaculture *per se* is exempt from these regulations if the grower does no processing, the processor will require information from the grower to include in his HACCP plan. Growers should be familiar with HACCP and the information pertaining to aquaculture drugs, environmental chemical contaminants and pesticides, which the processor will be required to evaluate and perhaps include as a Critical Control Point (receiving step) in his HACCP plan. Seafood processors, and growers who are also processors (by definition above), must have a trained individual to carry out the following tasks: 1) develop the HACCP plan; 2) reassess and modify the HACCP plan and hazard analysis; and 3) review HACCP records within a week following their recording. The regulation defines a trained individual as one who has "successfully completed training in the application of HACCP principles to fish and fishery product processing that is at least equivalent to that received under a standardized curriculum recognized as adequate by the USFDA, or who is otherwise qualified through job experience to perform these functions. Job experience will qualify if it has provided knowledge at least equivalent to that provided through the standardized curriculum." The standardized curriculum is the 2 1/2-day training course referred to in the introduction.

How HACCP works

The HACCP concept is built upon the following steps:

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs) in the process.
3. Establish critical limits.
4. Monitor each CCP.
5. Establish corrective actions.
6. Establish verification procedures.
7. Keep records and documentation.

A fish processor begins the HACCP process by creating a flow diagram of the process, and then conducts a hazard analysis of each step in the process to determine which ones, if not controlled, could result in human injury or illness. Hazards could be **biological** (pathogenic bacteria, viruses, parasites), **chemical** (natural toxins, pesticides, drug residues, unapproved food or color additives, and decomposition if it results in excessive histamine production), or **physical** (such as metal or glass fragments).

The intended use of the product by the consumer must be considered when assessing hazards. A product that will be fully cooked by the consumer requires a quite different HACCP plan than a product offered as a ready-to-eat (RTE) item. The method of packaging (i.e., over wrapped vs. vacuum packaged) and fresh vs. frozen also influence the HACCP plans for identical species. The final question in analyzing the hazard of each ingredient and processing step will be, "Is this step a Critical Control Point (CCP)?" If the answer is yes, then a HACCP plan must be developed to address that particular CCP. The plan will include setting critical limits, monitoring those limits, taking corrective actions if the limits are exceeded, establishing and carrying out verification procedures, and keeping records associated with each CCP. An example of a critical limit is the cooking time and temperature required to kill all pathogenic bacteria in a RTE product. A processor's critical limit also could be at the product receipt step in the process flow chart as shown in Figure 1.

Each process that involves one or more CCPs must have an associated HACCP plan. The plan may address one or several CCPs depending on the complexity of the process, the final product form, packaging type, etc.

Of the seven HACCP steps, record-keeping has been the most troublesome for the seafood industry. This can be explained by re-emphasizing the difference between the traditional inspection system and the HACCP system. Traditionally, a plant inspection involved evaluating processing practices on the day, or days, of the actual inspection, a "snapshot" so to speak. Using the same analogy, HACCP might be considered a "movie," in that the inspector not only will be evaluating plant operations on the day of inspection, but also will be reviewing required records since the last inspection.

Environmental contaminants and drugs

The publication "Fish and Fisheries Products Hazards & Controls Guidance," 3rd Edition, June, 2001, lists *all* aquaculture products as *potentially* posing a human health hazard from one or both of the following: 1) environmental chemical contaminants and pesticides and 2) aquaculture drugs. The manual describes in detail how to complete the hazard analysis, which is used to determine whether or not the potential hazard is significant. If the hazard is deemed significant then it must be considered a Critical Control Point (CCP) at either the "Pre-harvest" or the "Receiving" stage of processing.

In determining whether or not a hazard is significant, the recommended question to ask is, "Is it *reasonably likely* that unsafe levels of environmental chemical contaminants or pesticides will be introduced at the receiving step (e.g., does the raw material come in with an unsafe level of chemical contaminants or pesticides)? The answer generally is, "Yes, under ordinary circumstances it *would be* reasonably likely to expect that, without proper controls, unsafe levels of environmental chemical contaminants and pesticides could enter the process at the receiving step for all aquaculture species."

Figure 1.

Example HACCP Plan
Control Strategy-Supplier Certification

(1) Critical control point (CCP)	(2) Significant hazard(s)	(3) Critical limits for each preventive measure	(4) Monitoring: What	(5) Monitoring: How	(6) Monitoring: Frequency	(7) Monitoring: Who	(8) Corrective action(s)	(9) Records	(10) Verification
Receiving	Aquaculture drugs	Certificate indicating proper drug usage accompanying all lots of incoming pond-raised shrimp	Certificate indicating proper drug usage	Visual	Each lot received	Receiving dock employee	Reject lot AND discontinue use until supplier agrees to provide certificate for each lot	Growers drug usage certificate Receiving record	Visit all new pond-raised shrimp suppliers within the year and all suppliers at 25 percent per year on a rotating basis to review the growers' drug use procedures Review corrective action and verification records within one week of preparation

Certain geographic regions might be considered free of chemicals and pesticides based on historical land use, topographic features, or previous chemical sampling of soil by regulatory agencies or private industry. Open ocean net pen culture of finfish would be a good example. However, these instances would most likely be the exception, not the rule. (Environmental chemical contaminant and pesticide tolerances, action levels, and guidance levels are listed in Table 1.)

Therefore, environmental chemical contaminants and pesticides should be considered a significant hazard and addressed at the processing step (the Critical Control Point) where a preventive measure can be used to prevent, eliminate, or reduce the likelihood of occurrence to an acceptable level. As previously mentioned, for aquaculture products this processing step is either pre-harvest or receiving, and the suggested preventive measures are as follows:

1. **Pre-harvest** as a CCP:

   On-farm visits by the processor to collect soil, water and / or fish samples to be analyzed for chemical contaminants and pesticides that are reasonably likely to be present in the growing area.

2. **Receiving** as a CCP:

   A. Receipt of producer's lot-by-lot certification of harvesting from uncontaminated waters. If this method is chosen the processor should keep in mind that inspectors will expect to see a verification procedure appropriate for such a "self-reporting" system. For example, verification might include a visit to at least 25 percent of the suppliers each year to collect soil and / or water samples for chemical analyses and to observe and review agricultural and industrial practices in the growing area.

   B. Review of chemical / pesticide testing of fish flesh at the time of receipt for those contaminants likely to be present, and monitoring land use practices in the growing area. Testing and monitoring may be performed by the grower, a state agency or a private contractor.

   C. Chemical / pesticide testing of fish flesh at the time of receipt for likely contaminants. This is the responsibility of the processor and is carried out on each lot initially. However, processors can request the frequency of testing be reduced as a clean "track record" is established for certain producers.

   D. Receipt of evidence (i.e., a certificate) that the grower operates under a third-party- audited Quality Assurance Program that includes environmental chemical and pesticide analyses of soil, water and / or fish flesh.

The other major concern with farm-raised products is aquaculture drugs. As with environmental chemicals and pesticides, it is considered *reasonably likely* to expect that unsafe levels of aquaculture drugs *could* enter the process during receipt of any type of cultured fish. The preventive measures for control of aquaculture drugs are virtually identical to those listed above for chemicals and pesticides, ranging from pre-harvest on-site farm visits, to review of the grower's use (or non-use) of approved or investigational drugs, to third-party certification of a grower's use of aquaculture drugs. A list of USFDA-approved aquaculture drugs and low regulatory priority aquaculture drugs is in Table 2.

Summary

HACCP Programs are designed to prevent unsafe foods from reaching the consumer. Although producers of aquatic products are exempt from HACCP-related regulations, the processors of all aquaculture products will list *receiving* or *pre-harvest* as a CCP in their HACCP plans. Therefore, it is the responsibility of the producer to provide the processor with information concerning chemical contaminants and aquaculture drugs so that the processor can comply with his plan. Aquaculture producers who engage in any form of processing, such as eviscerating or heading, are considered processors and must follow the procedures to determine what, if any, HACCP plans they might need.

References

HACCP: Hazard Analysis and Critical Control Point Training Curriculum, 4th edition, November, 2001. Publication SGR 120 UF / IFAS Extension Bookstore, P.O. Box 110011, Gainesville, FL 32611-0011. (800) 226-1764.

Fish & Fisheries Products Hazards & Controls Guidance: 3rd edition, June, 2001. Available from USFDA Office of Seafood, 200 C St., SW, Washington, D.C. 20204. (202) 418-3133. Multiple copies available from UF / IFAS Extension Bookstore (above). Also available electronically at: *http://www.fda.gov*

Select "foods," then select "seafood," then select "HACCP."

In 2001 the Alliance introduced an internet, self-taught version of the 2 1/2-day HACCP course which, when coupled with 1 day of classroom instruction, will allow participants to receive a certificate of course completion issued by the Association of Food and Drug Officials (AFDO). The course can be found at *http://seafoodhaccp.cornell.edu*

A nationwide schedule of seafood HACCP courses can be found at *http://seafood.ucdavis.edu*

Table 1. (From: Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition)

Environmental Chemical Contaminant and Pesticide Tolerances, Action Levels, and Guidance Levels

Deleterious Substance	Level	Food Commodity	Reference
Aldrin/Dieldrin[a]	0.3 ppm	All fish	Compliance Policy Guide sec.575.100
Benzene hexachloride	0.3 ppm	Frog legs	Compliance Policy Guide sec.575.100
Chlordane	0.3 ppm	All fish	Compliance Policy Guide sec.575.100
Chlordecone[b]	0.3 ppm 0.4 ppm	All fish Crabmeat	Compliance Policy Guide sec.575.100
DDT, TDE, DDE[c]	5.0 ppm	All fish	Compliance Policy Guide sec.575.100
Diquat[d]	0.1 ppm	All fish	40 CFR 180.226
Fluridone[d]	0.5 ppm	Finfish and crayfish	40 CFR 180.420
Glyphosate[d]	0.25 ppm 3.0 ppm	Finfish Shellfish	40 CFR 180.364
Toxic elements: Arsenic	 76 ppm 86 ppm	 Crustacea Molluscan bivalves	 FDA Guidance Document FDA Guidance Document
Cadmium	3 ppm 4 ppm	Crustacea Molluscan bivalves	FDA Guidance Document FDA Guidance Document
Chromium	12 ppm 13 ppm	Crustacea Molluscan bivalves	FDA Guidance Document FDA Guidance Document
Lead	1.5 ppm 1.7 ppm	Crustacea Molluscan bivalves	FDA Guidance Document FDA Guidance Document
Nickel	70 ppm 80 ppm	Crustacea Molluscan bivalves	FDA Guidance Document FDA Guidance Document
Methyl mercury	1 ppm	All fish	Compliance Policy Guide sec.540.600
Heptachlor/ Heptachlor epoxide[e]	 0.3 ppm	 All fish	 Compliance Policy Guide sec.575.100
Mirex	0.1 ppm	All fish	Compliance Policy Guide sec.575.100
Polychlorinated biphenyls (PCBs)[d]	 2.0 ppm	 All fish	 21 CFR 109.30
Simazine[d]	12 ppm	Finfish	40 CFR 180.213a
2,4-D[d]	1.0 ppm	All fish	40 CFR 180.142

[a] The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin, do not count aldrin or dieldrin found below 0.1 ppm.

[b] Previously listed as Kepone, the trade name of chlordecone.

[c] The action level for DDT, TDE and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE and DDE, do not count any of the three found below 0.2 ppm.

[d] The levels published in 21 CFR and 40 CFR represent tolerances rather than guidance levels or action levels.

[e] The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, in adding amounts of heptachlor and heptachlor epoxide, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.

Note: The term “fish” refers to fresh or salt water finfish, crustaceans, mollusks and other forms of aquatic animal life, other than birds or mammals. Substances and values may change. Check with the appropriate agency for current listings.

Table 2. (From: Fish & Fishery Products Hazards & Controls Guidance, 3rd edition)

FDA-approved aquaculture drugs with their approved sources, species and withdrawal times are listed below. Additional details on conditions of use (e.g., disease condition and dosage levels) can be obtained from the Code of Federal Regulations as cited with each drug, or on the Web at *www.fda.gov/cvm/index/aquaculture*.

Chorionic gonadotropin:	Intervet, Inc., Millsboro, DE; may be used as an aid in improving spawning function in male and female brood finfish, (CFR 522.1081).
Formalin solution:	Natchez Animal Supply Co., Natchez, MS or Argent Laboratories, Redmond, WA; may be used only in salmon, trout, catfish, large-mouth bass and bluegill for the control of protozoa and monogenic trematode, and on the eggs of salmon, trout and pike (esocids) for the control of fungi of the family *Saprolegniacea* (21 CFR 529.1030).
Formalin solution:	Western Chemical, Inc., Ferndale. WA; may be used to control external protozoa and monogenic trematode on all finfish species, external protozoan parasites on shrimp, and fungi of the family *Saprolegniacea* on the eggs of all finfish species (21 CFR 529.1030).
Tricaine methanesulfonate (MS-222):	Argent Laboratories, Redmond, WA or Western Chemical, Inc., Ferndale, WA; may be used only in the families *Ictaluridae* (catfish), *Salmonidae* (salmon and trout), *Esocidae* (pike) and *Percidae* (perch) when the fish is intended to be used for food. It may not be used within 21 days of harvesting fish for food. In other fish and in cold- blooded animals, the drug should be limited to laboratory or hatchery use (21 CFR 529.2503).
Oxytetracycline:	Pfizer, Inc.; for feed use; may be used only in salmonid, catfish and lobster culture. Withdrawal times are: marking in Pacific salmon, 7 days; disease control in salmonids, 21 days; catfish, 21 days; lobster, 30 days (21 CFR 558.450). Oxytetracycline tolerance in flesh is 2.0 ppm (21 CFR 556.500).
Sulfamerazine:	Roche Vitamins, Inc.; may be used only in trout. It may not be used within 21 days of harvest (21 CFR 556.660). Note: This product currently is not marketed.
Sulfadimethoxine/ormetoprim combination:	Alpharma, Inc.; may be used only in salmonids and catfish. Withdrawal times are: salmonids, 42 days; catfish, 3 days (21 CFR 558.575). Tolerance in the flesh is 0.1 ppm for both drugs (21 CFR 556.640).

The following is a list of low regulatory priority aquaculture drugs. FDA is unlikely to object to the use of these drugs if the following conditions are met: 1) substances are used for the stated indications; 2) substances are used at the prescribed levels; 3) substances are used according to good manufacturing practices; 4) the product is of an appropriate grade for use in food animals; and 5) there is not likely to be an adverse effect on the environment.

Acetic acid:	Used in a 1,000 to 2,000 ppm dip for 1 to 10 minutes as a parasitide for fish.
Calcium chloride:	Used to increase water calcium concentration to ensure proper egg hardening. Dosages used would be those necessary to raise calcium concentration to 1 to 20 ppm $CaCO_3$. Used at up to 150 ppm indefinitely to increase the hardness of water for holding and transporting fish in order to enable fish to maintain osmotic balance.
Calcium oxide:	Used as an external protozoacide for fingerlings to adult fish at a concentration of 2,000 ppm for 5 seconds.

Table 2. (continued)

Carbon dioxide gas:	Used for anesthetic purposes in cold, cool and warm water fish.
Fuller's earth:	Used to reduce the adhesiveness of fish eggs to improve hatchability.
Garlic (whole form):	Used for control of helminth and sea lice infestations of marine salmonids at all life stages.
Hydrogen peroxide:	Used at 250 to 500 ppm to control fungi on all species and life stages of fish, including eggs.
Ice:	Used to reduce metabolic rate of fish during transport.
Magnesium sulfate:	Used to treat external monogenic trematode infestations and external crustacean infestations in fish at all life stages. Used in all freshwater species. Fish are immersed in a 30,000 ppm $MgSO_4$/7,000 ppm NaCl solution for 5 to 10 minutes.
Onion (whole form):	Used to treat external crustacean parasites and to deter sea lice from infesting external surface of salmonids at all life stages.
Papain:	Used in a 0.2% solution to remove the gelatinous matrix of fish egg mass in order to improve hatchability and decrease the incidence of disease.
Potassium chloride:	Used as an aid in osmoregulation; relieves stress and prevents shock. Dosages used would be those necessary to increase chloride ion concentration to 10 to 2,000 ppm.
Providone iodine:	Used in a 100 ppm solution for 10 minutes as an egg surface disinfectant during and after water hardening.
Sodium bicarbonate:	Used at 142 to 642 ppm for 5 minutes as a means of introducing carbon dioxide into the water to anesthetize fish.
Sodium chloride:	Used in a 0.5% to 1.0% solution for an indefinite period as an osmoregulatory aid and for the relief of stress and prevention of shock, and in a 3% solution for 10 to 30 minutes as a parasitide.
Sodium sulfite:	Used in a 15% solution for 5 to 8 minutes to treat eggs in order to improve their hatchability.
Thiamine hydrochloride:	Used to prevent or treat thiamine deficiency in salmonids. Eggs are immersed in an aqueous solution of up to 100 ppm for up to 4 hours during water hardening. Sac fry are immersed in an aqueous solution of up to 1,000 ppm for up to 1 hour.
Urea and tannic acid:	Used to denature the adhesive component of fish eggs at concentrations of 15 g urea and 20 g NaCl per 5 liters of water for approximately 6 minutes, followed by a separate solution of 0.75 g tannic acid per 5 liters of water for an additional 6 minutes. These amounts will treat approximately 40,000 eggs.

SRAC fact sheets are reviewed annually by the Publications, Videos and Computer Software Steering Committee. Fact sheets are revised as new knowledge becomes available. Fact sheets that have not been revised are considered to reflect the current state of knowledge.

The work reported in this publication was supported in part by the Southern Regional Aquaculture Center through Grant No. 2002-38500-11085 from the United States Department of Agriculture, Cooperative State Research, Education, and Extension Service.