



The Seafood HACCP Regulation and Its Effects on Aquaculture

Introduction

In December 1997 the United States Food and Drug Administration (FDA) began to enforce regulations to increase the safety of the U.S. food supply by requiring fish processors to use preventive controls to keep unsafe products from reaching consumers. These new FDA regulations represented a new way in which food is protected. The regulations are based on principles of a system called Hazard Analysis Critical Control Point (HACCP) and focus on a process of preventive rather than reactive measures.

Under these procedures fish processors take greater responsibility in preparing safe fishery products, and government and industry work more closely together to protect the consumer. The mandatory regulation is based on the belief that every fish processor, through proper training or experience, can understand the food safety hazards of their products and take reasonable steps to keep them from happening. HACCP training is achieved through course materials or job experience that provides knowledge equivalent to a standard curriculum course recognized as adequate by the FDA. Processors may either obtain training for one or more of their own employees or they may hire trained independent contractors to perform the HACCP functions.

HACCP consists of identifying safety hazards, determining where they occur, establishing critical limits to deal with the hazards, monitoring these points, and recording the results. HACCP involves day-to-day monitoring of critical control points by production employees. The seafood HACCP regulation is based on the belief that commercial fish processors can understand the food safety hazards of their products and take reasonable



steps to control them. The HACCP regulation requires processors to keep extensive records of processing and sanitation at their facilities.

The seven HACCP principles include:

1. Conduct a hazard analysis
2. Determine all critical control points
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record keeping and documentation

In March 2016, jurisdiction and regulatory oversight over Siluriformes fish (including major catfish species) and fish products changed from the FDA to the Food Safety



Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA). So, those who produce and process catfish are no longer under the jurisdiction of the FDA but under the jurisdiction of the USDA. Siluriformes fish that are harvested for use as human food must be raised under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food. Thus FSIS has developed standards for catfish aquaculturists to follow, including site selection for ponds, water quality standards, and harvesting and transportation practices. Catfish that arrive at a fish processing facility must be healthy and alive.

At times, questions arise as to whether someone needs training in seafood HACCP. The seafood HACCP regulation defines processing as handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding fish or fishery products. The FDA regulation does not apply to the harvest or transport of fishery products, but the USDA regulation related to catfish does include standards for harvest and transport to fish processing facilities. Retail establishments are also exempt from the seafood HACCP regulation.

Identification of Hazards and Their Control

The key HACCP components are identification of biological, chemical, and physical hazards that could make fishery products unsafe; establishment and monitoring of targeted control points to minimize such hazards; corrective actions to be taken if a hazard is identified; and keeping records of the results. Biological hazards include bacteria, viruses, and parasites that if present in a fishery product could pose a human health threat when consumed. Chemical hazards include aquaculture drugs and environmental chemicals, and these need to be absent or within acceptable regulatory levels in the finished processed fish product. Physical hazards include such things as metal, plastic, or wood fragments that could get into processed fish products from the aquaculture operation or fish processing equipment.

Under the FDA regulations (USDA for catfish), fish processors will have to identify hazards that, without preventive controls, are reasonably likely to affect the safety of the product. If at least one hazard is identified, the firm will be required to adopt and implement an appropriate HACCP plan. Fish processors using the HACCP system will continue to be monitored under FDA surveillance and inspection programs (USDA for catfish). In addition, states have food safety inspectors that monitor the compliance of fish processors with seafood HACCP. The HACCP records kept by the fish processor enable regulators to monitor product safety more closely and on a more continuous basis than through spot checks. Proper use of approved aquaculture drugs and prevention of product contamination with environmental chemical contaminants and agricultural chemicals will be the main hazards identified in fish produced in aquaculture operations.





Sanitation Standard Operating Procedure

The USDA regulation for catfish requires each processor to have and implement a written sanitation standard operating procedure (SSOP), or similar document, specific to each location where fish and fishery products are produced. The FDA regulation only requires processors of fish other than catfish to keep records of sanitation procedures. The SSOP should specify how the processor will meet those sanitation conditions and the practices that are to be monitored. The law requires each processor to monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices that are both appropriate to the fish processing plant and the food being processed. Each processor shall maintain sanitation control records that document both the monitoring and corrections. The processor shall correct in a timely manner those conditions and practices that are not met. Sanitation controls may be included in the HACCP plan, however if the controls are adequately monitored and adequate records are kept they need not be included.

The eight key sanitation conditions that must be met include:

1. Safety of the water that comes in contact with food or food contact surfaces, or is used in the manufacture of ice
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments

3. Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and other outer garments, and from raw product to cooked product
4. Maintenance of hand washing and sanitizing facilities, and toilet facilities
5. Protection of food, food packaging materials, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants
6. Proper labeling, storage, and use of toxic compounds
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces
8. Exclusion of pests from the food plant

Aquaculturists Directly or Indirectly Affected by HACCP

Aquaculturists who process their own fish will be directly affected by the HACCP regulation. Those that sell their fish to a processor will be indirectly affected by the HACCP regulation even if they do not use aquaculture drugs during the production of their fish. Processors of domestic as well as imported fishery products will take greater responsibility for incoming materials which will directly affect aquaculture producers.





Aquaculture Drugs and Chemical Contaminants as Potential Hazards

Use of unapproved drugs or misuse of approved drugs in aquacultured fish poses a potential human health hazard. These substances may be toxic, allergenic, or carcinogenic, or may cause antibiotic resistance in pathogens that affect humans. To control this hazard, drugs for use in food animals, whether they are for direct medication or a feed additive, generally must be approved, conditionally approved, or index listed by the FDA. Under certain conditions authorized by the FDA, unapproved new animal drugs may be used in conformance with the terms of an Investigational New Animal Drug (INAD) application. Off label use in animals of approved human or animal drugs is permissible in certain circumstances. Drugs on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) may not be used in food animals except in early nonfood life stages of food producing minor species in certain circumstances.

The uses of drugs in aquaculture include the need to treat and prevent diseases, control parasites, affect reproduction and growth, and provide tranquilization. Thus far, relatively few drugs have been approved for aquaculture use. Because of this, it may lead to the inappropriate use of unapproved drugs, general-purpose chemicals, or approved drugs in a manner that deviates from the labeled instructions. Aquaculturists who sell their fish to a fish processor will be expected to work out some type of arrangement that will help ensure the safety of their product even if they do not use aquaculture drugs in their operations.

The fish processor or one of their representatives may visit the fish farm one or more times per year to observe proper use of aquaculture drugs and agricultural and industrial practices near the fish production facility. At this time fish samples may be collected to perform tests for drug residue, environmental chemical contaminants, and pesticide analyses. The aquaculturist may also perform these same duties and provide a certificate of guarantee to the fish processor with each lot of fish sold, verifying that these specific areas were monitored. A third party certificate is also allowable if the aquaculturist operates under a Quality Assurance Program that covers aquaculture drug usage, environmental chemical contaminants, and pesticides.

If the supplier, such as an aquaculture producer, does not provide satisfactory information about how the fish were handled, the HACCP plan will strengthen the processor's position in refusing to accept the shipment. Aquaculture producers will thus be responsible for providing specific information to fish processors who purchase their fish or allowing these fish processors or their representatives to visit their farm sites to collect information on their aquaculture practices. This information may include proper use of approved aquaculture drugs and withdrawal times, and prevention of product contamination with environmental chemical contaminants and agricultural chemicals.

Aquaculturists can expect to bear increased responsibility for documenting compliance with the HACCP regulations, as it seems doubtful the FDA or USDA will permit the direct sale of aquaculture products to end users without HACCP controls even when fish production, harvesting, trucking, and retail are excluded in the FDA regulation. The USDA has standards for catfish aquaculturists to follow related to fish production, harvesting, and transportation to fish processing facilities.



It is recommended that aquaculturists develop a good working relationship with their fish processor. The fish processor will work with the aquaculturist under a “trust but verify program” to ensure the credibility of the HACCP program. There are a variety of control strategies that fish processors and aquaculturists can cooperate on that include on-farm visits, supplier’s certifications, records of drug use, drug residue testing, Quality Assurance Programs, and controls during holding.

Practices Exempt from the HACCP Regulation

There are some practices that are exempt from the federal HACCP regulations, but the aquaculture producer will still need to comply with specific state and local regulations where applicable. For instance, an aquaculture producer would not be subject to FDA HACCP regulations when harvesting and boxing fish whole on ice for immediate transportation to a wholesaler or retailer within the state or outside the state. The aquaculture producer would not be subject to the HACCP regulation if selling boxed whole fish to a wholesaler at the farm site and the wholesaler transported the fish off the farm to a retail market or if the producer did the transportation. But, if the aquaculture producer holds the product after harvesting and prior to distribution for 24 hours or more, that operation would be subject to the regulations. Holding is deemed processing as defined in the HACCP regulation. If the aquaculture producer performs any other activities as defined in the regulations such as heading, eviscerating, or freezing, they would be subject to the regulations.



Other practices that are exempt from the federal HACCP regulations include live fish hauling to various market outlets, custom processing the fish directly for the consumer who does not resell it, and fee fishing operations. Fish may be taken to some location in the same state or may be taken to another state for consumption.

Conclusions and Recommendations

Aquaculture producers who do not process their own fish may not be directly affected by the HACCP regulations but may in many ways be affected indirectly. It is important that all aquaculture producers take it upon themselves to become aware of the HACCP regulations to circumvent any surprises when it comes time to market their fish. Many aquaculturists have been under the impression that if they do not use aquaculture drugs the seafood HACCP regulation would not apply to them. Even those aquaculturists who do not use aquaculture drugs must prove through testing that aquaculture drugs are not in the tissue of the fish that they sell to fish processors.

Aquaculturists who complete a seafood HACCP course put themselves at a competitive advantage as they can then become their own fish processor. This allows them to produce value added products, such as processed fillets and smoked fish, which command a higher price in the marketplace when compared to selling their whole fish directly to a fish processor.





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All photos courtesy of Ronald E. Kinnunen

Disclaimer

Local, state, and federal regulations relating to processing and food safety are continually subject to change. Always stay informed of the most up-to-date regulations that may impact your operation.

Suggested Readings and Information Resources

Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition. April 2011. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition. <https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM251970.pdf>

FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products. March 2017. Food Safety Inspection Service, U.S. Department of Agriculture. <https://www.fsis.usda.gov/wps/wcm/connect/8ec92a7f-8f9b-45ae-b80f-7c336f7d6ff5/Compliance-Guideline-Siluriformes-Fish.pdf?MOD=AJPERES>

Sanitation Control Procedures for Processing Fish and Fishery Products. 2000. National Seafood HACCP Alliance for Training and Education. <http://marketyourcatch.msi.ucsb.edu/sites/marketyourcatch.msi.ucsb.edu/files/docs/resources/Seafood%20HACCP%20Alliance%202000%20Intro%20Sanitation%20Control%20Procedures.pdf>



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