# Development and Efficacy of HACCP in the Fish Industry

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**Abstract**

HACCP is a science-based system of preventive controls for food safety that commercial seafood processors develop to identify potential food safety hazards and implement to keep them from occurring. The FDA Seafood HACCP program was designed to increase the margin of safety that consumers already had and to reduce those illnesses that do occur to the lowest possible levels. This paper will describe the development of HACCP within the Seafood Industry and provide a brief overview of what is involved with this system. The implications of the complexity of the fish industry will be discussed in comparison with the meat and poultry industry, which is under a different HACCP program dictated by the USDA. The impact of HACCP on international trade has varied among countries, with developing countries requiring some external support for implementation. Several criticisms and compliments of the seafood HACCP program will be discussed, along with a look at the direction of this program in the near future.

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**Introduction to History of the Fishing Industry**

The fishing industry includes any business or activity concerned with culturing, processing, preserving, storing, transporting, marketing or selling fish or fish products. This industry goes back to the start of human civilization, and continues to be a major part of the global food chain today.[1] Not only does fish provide a crucial source of protein and nutrition for many people, but the industry is also vital to the economies of many countries. The livelihoods of over 500 million people in developing countries depend on fisheries and aquaculture.[2]

There are three major fish industry divisions. The *commercial sector* consists of enterprises and people associated with wild-catch or aquaculture resources and transformations of such into sale products. While primarily considered the "seafood industry", this sector also includes non-food items such as pearls and various shells. The *traditional sector* includes individuals and activities associated with fisheries resources from which aboriginal people derive products through their traditional practices. The *recreational sector* is comprised of activities with fisheries resources for the purpose of recreation, sport or sustenance, where the products that are derived are not for sale.[3] The Australian Fisheries Research and Development Corporation provides more detail for the commercial sector, as it is the one responsible for most of the fish we eat, and that is involved in international trade.[4]

*Commercial sector:*

[1] FAO. 2008. Report of the FAO expert workshop on climate change implications for fisheries and aquaculture. Rome, Italy, 7–9 April 2008. FAO Fisheries Report No. 870
[2] *Id.*
[3] *Id.*
[4] "About Fish". Australian Government. Fisheries Research and Development Corporation. Copyright 2009 FRDC. http://www.frdc.com.au/aboutfish/about-fish Retrieved 2/13/10

The commercial segment is involved in the delivery of fish and other seafood products for human consumption or for input factors in other industrial processes. The chain of events is typically as follows: commercial fishing and fish farming produces the fish, then fish processing to produce the fish products, and finally marketing of the fish products.[5]

According to the Food and Agriculture Organization (FAO), the world harvest in 2005 consisted of 93.3 million tonnes captured by commercial fishing in wild fisheries, plus 48.1 million tonnes produced by fish farms.[6] In addition, 1.3 million tons of aquatic plants (such as seaweed) were captured in wild fisheries and 14.8 million tons were produced by aquaculture. This amounts to about 24.4 kilograms a year for the average person on Earth.[7] The top producing countries in descending order were; the People's Republic of China (excluding Hong Kong and Taiwan), Peru, Japan, the United States, Chile, Indonesia, Russia, India, Thailand, Norway and Iceland. Those countries accounted for more than half of the world's production; China alone accounted for a third of the world's production.[8]

Since the 1990s, it has been of growing concern that industrial fishing is depleting stocks of certain ocean fish, such as cod or oysters. As a result, practices such as fish farming have become increasingly used. Aquaculture is one technique, which is the cultivation of aquatic populations under controlled conditions.[9] Another method is fish farming, which involves raising fish commercially in tanks or enclosed pools, usually for food. Fish species raised by fish farms include carp, salmon, tilapia, catfish and cod. Increasing demands on wild fisheries by commercial fishing operations have caused widespread overfishing. Fish farming offers an

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[5] FAO. 2008. Report of the FAO expert workshop on climate change implications for fisheries and aquaculture. Rome, Italy, 7–9 April 2008. FAO Fisheries Report No. 870

[6] "Fisheries and Aquaculture". Food and Agriculture Organization of the United Nations. Copyright FAO 2010. Retrieved 3/1/10

[7] *Id.*

[8] *Id.*

[9] ""Aquaculture." Britannica Concise Encyclopedia. 2010. Copyright 2010 Encyclopedia Britannica, Inc. 2/15/10

alternative solution to the increasing market demand for fish and fish protein. While this process of fish farming has been very effective in increasing the production of such fish, it is not without its downfalls. There are some concerns regarding the differing diets that these fish may receive compare to that of in the wild (such as being fed corn), which may make them less nutritious. Also, confined fish may be more vulnerable to toxins or unsanitary conditions (e.g. feces of other fish) in their environmental waters.[10]

The fish delivered by commercial fisheries and fish farms then undergo processing. The larger fish processing companies have their own fishing fleets and independent fisheries. The products of the industry are usually sold to grocery chains or to other retail locations. Fish processing consists of two components: fish handling, which is the initial processing of raw fish, and fish products manufacturing.[11] Aspects of fish processing can take place on fishing vessels and at fish processing plants. Another way to divide the fish processing practice is into the "primary" processing of filleting and freezing of fresh fish for distribution to fresh fish retail, and the "secondary" processing that generates chilled, frozen and canned products for the retail and catering trades.[12]

Fish products, also referred to as 'seafood products', are estimated to provide about 16% of the world population's protein.[13] There are many edible species of fish which are a valued source of food for numerous populations. Other marine life utilized as food includes shellfish, crustaceans, sea cucumber, jellyfish and roe. Fish and other marine life are also used for many other purposes, such as jewelry (e.g. pearls). Some traditional Chinese medicines are derived from some species such as sea horses, star fish, sea urchins and sea cucumber. Fish emulsion is a

[10] *Id.*
[11] Inquiry into the Future of the Scottish Fishing Industry". The Royal Society of Edinburgh. March 2004. From, http://www.royalsoced.org.uk/enquiries/scottishfisheries/scottish_fishing_industry.pdf.
[12] *Id*.
[13] *Id*.

mixture that is produced from the fluid remains of processed fish processed, and makes for a good organic fertilizer.[14] Fish products then make their way to fish markets, which are the marketplaces used for the trade and sale of fish and other seafood. They can be dedicated to wholesale trade between fishermen and fish merchants, or to the sale of seafood to individual consumers, or to both. The live food fish trade is a system that links fishing communities with markets around the world. [15]

**Historic Cases of Seafood-Borne Illnesses**

During the summer of 1981, several cases of cases of gastroenteritis and one wound infection due *to Vibrio parahaemolyticus* were reported to public health agencies in Washington and Oregon. A report by Nolan et al. (1984) in *Diagnostic Microbiology and Infectious Disease* described this new epidemiologic pattern of *V. parahaemolyticus* infection at the time.[16] The scientists found that all of the gastroenteric illnesses were associated with eating raw oysters. The majority of the oysters the ill patients had consumed had been harvested at four sites at Willapa Bay, Washington - a large commercial growing area. It had been repeatedly observed that most environmental isolates of V. *parahaemolyticus* are Kanagawa negative, whereas most strains isolated from patients with gastroenteritis are Kanagawa positive.[17] The authors suggested that environmental strains of V. *parahaemolyticus* acquire Kanagawa positivity when passing through the human gut.[18] This investigation demonstrated that the geographic distribution of V. *parohaemolyticus* infection in the United States included the Pacific seacoast. Furthermore, it

[14] *Id*.
[15] Shang YC, Leung P, Ling BH (1998). Comparative economics of shrimp farming in Asia. *Aquaculture.* Vol. 164 (1). May 1 1998. Pages 183-200
[16] Nolan C, Ballard J, Kaysner C, Lilja J, Williams J, Tenover F. (1984) Vibrio parahaemolyticus gastroenteritis: An outbreak associated with raw oysters in the pacific northwest *Diagnostic Microbiology and Infectious Disease*; Volume 2(2), April 1984, Pages 119-128
[17] Id.
[18] Thompson CA Jr, Vanderzant C, Ray SM (1976) Serological and hemolytic characteristics of *Vibrio parahaemolyticus* from marine sources. J Food Sci 41:204.

highlighted the capability of oysters as being a potential infection transmission vehicle, along with other seafood, in the United States.[19]

In 1987, a paper was published in *Journal of American Medical Association* describing a case where several physicians who attended a conference held at a New Hampshire inn severe developed headaches and redness of the upper part of the body within four hours of eating bluefish which was served at lunch.[20] Further investigation of this incident was obtained through distribution of questionnaires that asked about food consumption and symptoms to 55 faculty and participants who stayed at the same hotel for the conference. Samples of the bluefish fillets were also collected from the inn and analyzed for levels of histamine, putrescine, and cadaverine. This study found that the originally frozen bluefish had been improperly handled during storage and thawing.[21] Elevated levels of histamine, putrescine, and cadaverine were detected in uncooked samples. The authors concluded that this outbreak emphasized that scombroid-type poisoning can be not only caused by nonscrombroid fish (such as bluefish), but that such poisoning may be more common than realized and of rising concern with the increasing consumption of fish in the American diet. The authors suggest that these findings indicate the need for physicians and public health officials to help prevent additional cases and outbreaks.[22]

In 1985, a study was conducted to examine risk factors associated with *V vulnificus* infections in the Southern Louisiana area. This was a regional case-control study of 19 patients identified by isolates received at a state reference laboratory. Interviews with patients or surviving relatives and with three controls for each patient were compared in a matched analysis.

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[19] Nolan, *supra* note 16
[20] Etkind P, Wilson E, Gallagher K, Cournoyer J (1987). Bluefish-Associated Scombroid Poisoning. *JAMA* Dec 18, 1987; Vol258 (23).
[21] *Id*.
[22] *Id.*

Patients with *V vulnificus* wound infection were more likely than controls to have sustained a puncture wound while handling fresh seafood or to have been exposed to salt water.[23] Of prime concern, more patients with primary septicemia than controls had eaten raw oysters before the onset of illness. Although *V vulnificus* infection is unusual, with a regional incidence of 0.8 per 100,000 people, septicemia in the immune-suppressed patient is a very serious illness.[24] The authors concluded that such risk could be prevented by not eating raw seafood, since *V vulnificus* is commonly found in coastal waters.

Episodes such as these three listed, and increasing awareness of the potential risk that seafood can possess in relation to human health, highlighted the escalating need for safety regulations of the seafood supply.

**The Development of HACCP**

In 1997, the US Food and Drug Administration (FDA) enacted regulations that govern the safe processing and importing of fish and fishery products as a preventative approach to food safety.[25] This included the identification of biological, chemical, and physical hazards, followed by process controls to minimize the risk of food-borne illness. This methodology formulated the basis of "Hazard Analysis and Critical Control Point", often referred to as HACCP.

The concept for HACCP originated in 1959 when NASA requested that the Pillsbury Company develop a food system which assured safe food for their astronauts. NASA wanted their food to be 100% safe, which the traditional end-product testing would not satisfy as too much product than feasibly possible would have to undergo testing to meet the statistical

[23] Johnston J, Becker S, McFarland L. (1985). *Vibrio vulnificus*: Man and the Sea. JAMA 1985; Vol.253(19), 2850-2853
[24] *Id*.
[25] Miget R. The HACCP Seafood Program and Aquaculture. *Southern Regional Aquaculture Center.* Publication No. 4900, February 2004

requirement for absolute safety.[26] This was a turning point in the US food industry which really brought into question how safe our food supply truly was. This was also a time when people began to wonder what developments in new technology could do to assure greater safety for the general public; not just the astronauts.

HACCP was developed to be a preventative system controlling raw materials, processes, environment, personnel, storage, and distribution early in the system. Its intentions were to eliminate the need for routine end-product testing by combining these preventative measures with sufficient record keeping.[27] End-product testing could then be simply used as a means of verifying that the system is working properly. HACCP's purpose is with regard to safety only, and does not control food quality or replace Good Manufacturing Practices (GMPs). Undesirable items in a food product (such as hair, pebbles, or filth), are not considered unsafe and thus would not be controlled by HACCP practices. GMPs control the sanitation and personal hygiene at the plant, and require significantly less stringent record keeping than that required for food safety.[28]

The National HACCP Alliance has developed a standardized curriculum for HACCP practices, including control guides listing more than 250 species of finfish, 80 species of invertebrates, all with a corresponding species-related hazard.[29] Many view the fish industry as exceedingly more complex than the meat and poultry industry, given the broad range of species of fish and the numerous ways of preparation. The guide describes the hazards of various processing methods, such as ready-to eat foods, smoked, dried, etc. This alliance also offers a training course that can be completed within three days.

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[26] Miget, *supra* note 25
[27] *Id*.
[28] *Id*.
[29] *Id*.

The regulations for seafood processing were established in the December 1997 Code of Federal Regulations. Importers and processors must both comply with the regulations, whether they are international or domestic. An importer is defined to be "either the US owner or co-signee at the time of entry into the US, or the US agent or representative of the foreign owner or consignee at the time of entry into the US, who is responsible for ensuring that goods being offered for entry into the US are in compliance with all laws affecting the importation".[30] It is the responsibility of the importer to obtain the fish product from a country that has an active Memorandum of Understanding (MOU), or similar agreement with the USFDA that documents the compliance of the relevant country's inspection system with the US system. Another option is for the importer to have written verification which ensures that the foreign country's products were processed in a manner that corresponds with the regulation requirements.

A processor is defined to be any person "engaged in commercial, custom, or institutional processing of fish or fishery products, either in the US or in a foreign country".[31] The practice of processing includes: handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.[32] The regulations do not apply to: harvesting or transporting fish/fishery products; practices such as heading, eviscerating, or freezing for purposed of preparing a fish or for holding on a harvest vessel; or the operation of a retail establishment.[33] It is the role of the seafood processor to have a trained individual perform the tasks of developing a HACCP plan, reassess and modifying such a plan and/or hazard analysis when appropriate, and review the

[30] Seafood HACCP Regulation: Fish and Fisheries Products Hazards and Controls Guidance. June 2001. www.fda.gov.
[31] *Id*.
[32] *Id*.
[33] *Id*.

HACCP records within a week of their recording.[34] To qualify as an individual capable of performing these tasks, the person must have completed training in the application of HACCP principles to fish, or have had equivalent job experience to execute such activities.[35]

As a result of the FDA regulations, the national Seafood HACCP Alliance developed a standardized 3-day training curriculum for seafood firms and regulatory personnel who do the inspecting to better understand the HACCP concept and specific seafood safety concerns. For several years, hundreds of training programs were conducted across the United States. This shifted around 2000, when there was a significant decrease in the number and frequency of available training workshops, as many trainers became involved in other issues.[36] It was a real challenge in the seafood industry to have a representative travel for training for three consecutive days. Also, the person who was sent for the training might not always be a person involved in day to day implementation. There appeared to be a need for additional people to be trained. It was not unusual at this time for individuals who needed this training to wait for more than a year for a local workshop to become available. This issue was addressed through funding support from the CSREES/USDA Food Safety and Quality Competitive Grant Program to develop an internet-based Seafood HACCP distance education training program in collaboration with FDA and the National Seafood HACCP Alliance. [37]

This online training program consisting of 12 interactive training modules was completed in 2001. It became clear that much of the first 2 days of original 3 day training was an introduction to HACCP principles, which could easily be delivered by online instruction. Thus,

[34] Miget, *supra* note 25
[35] *Id*.
[36] Gall, Ken (2005). Cornell University College of Agriculture and Life Sciences: HACCP food safety training for seafood processors and regulatory agencies via the Internet-*2004 Impact statement*
[37] *Id*.

the internet based format combined the first 2 days of training online, and then required 1 day of travel to get a hands on sense of HACCP implementation.[38] The online course is low cost (approximately $50 per student) and accessible on-demand to individuals with a wide range of skills and internet access. It is based out of the Cornell Cooperative Extension server and is managed by the New York Sea Grant program. Over 1,000 individuals from 48 states and 19 foreign countries enrolled in this internet-based training course from 2001 to the beginning of 2005.[39]

By the end of 2004, approximately one-third of all individuals in the U.S. who needed this training utilized this Internet-based distance education program. There is no test to assess how well the individuals learned the HACCP material; the main concept is to educate of the safety concerns, and then individuals can refer to the HACCP guide for specifics.[40] A concern may be how much information is intended to be absorbed within a relatively short period of time. However, the feasibility of this on-demand training has been argued to allow seafood firms to implement and modify food safety controls in a timelier manner. Members of the National Seafood HACCP Alliance feel this will ultimately improve compliance with current regulations and enhance the safety of the nation's seafood supply.[41]

**Description of HACCP Steps and Regulations**

HACCP is comprised of 7 fundamental steps, as described below:

1) *Execute a hazard analysis*: Upon creating a diagram of the entire process, the fish producer conducts a hazard analysis at each step to determine which ones could result in human illness or

[38] Gall, *supra* note36
[39] *Id*.
[40] Gall, Ken (Sea Grant Seafood Specialist from New York Sea Grant) Telephone Interview. March 30, 2010
[41] Gall*, supra* note 36

injury if not controlled. When identifying potential hazards, the intended use of the product must be considered. For example, a fish product that will be thoroughly cooked by the consumer would require a different analysis than a product which is intended to be ready-to-eat (RTE).[42] Hazards can be of biological (e.g. parasites), chemical (e.g. pesticides or drug residues), or physical (e.g. metal fragments) nature.

2) *Identify Critical Control Points (CCPs):* A CCP decision tree is utilized for this step. This consists of a series of 'yes' or 'no' questions which lead to another question, such as:
Q1. Could the hazard be present in or on the product at unacceptable levels at this step?
A. *Yes*: give reasons and go on to next Q; *No*: not a CCP; proceed to next identified hazard

Q2. Is there a control measure available at this step that would prevent unacceptable levels of the hazard?
A. *Yes*: this step is a CCP, answer Q3; *No*: not a CCP

Q3: Is there a control measure available at a previous step that would significantly contribute to preventing unacceptable levels of the hazard at this step?
A: *Yes*: retrospectively assign the previous step as a CCP; *No*: if the answer to Q was also no, consider whether addition of further steps could control the hazard or whether redesigning the process is necessary for ensuring the availability of a control measure. At the end, one should proceed to the next identified hazard.[43]

[42] Miget, *supra* note 25
[43] Lee, J. A., and Hathaway, S. C. (1998). The challenge of designing valid HACCP plans for raw food commodities, Food Control, *9*(2/3), 111–117.

Following such a series of questions will identify the critical control points that require further attention within a HACCP plan.

3) *Establish critical limits:* The HACCP must include a list of the critical limits that must be met at each of the critical control points. A critical limit is a standard that separates an acceptable level from an unacceptable level of a particular parameter. Some critical control points have more than one critical limit. These critical limits often involve temperature, moisture level, pH, water activity, and sensory cues such as visual appearance and texture.[44] A variety of sources are responsible for determining a critical limit, such as "government regulations and guidelines, both in your own and in the importing country, or international codes of practice, industry guidelines, literature surveys, experimental studies and/or through the advice of experts with working knowledge of the industry".[45] Before the HACCP system is finalized and implemented, it should be validated that the critical limit will control the specified hazard.

4) *Monitor each CCP:* A list of the procedures that will be used to monitor each of the CCPs established must be included. The frequency of such monitoring must also be ascertained to ensure adherence to the critical limits.[46] Some companies are attempting to monitor CCPs electronically, and others are developing interactive multimedia training programs.[47]

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[44] "An Introduction to HACCP for Fish Processors". ASEAN-Canada Fisheries Post-Harvest Technology Project. Asean Coordinating Office; Network of Fisheries Post-Harvest Technology Centres. From http://www.revistaaquatic.com/aquatic/html/art303/Anexo1.htm

[45] *Id*.

[46] FDA Seafood HACCP regulation, *supra* note 30

[47] Tzouros NE and Arvantioyannis IS. Implementation of Hazard Analysis Critical Control Point (HACCP) System to the Fish/Seafood Industry: A Review. Food Rev.Int., 16(3) 2000: 273-325.

5) *Establish Corrective Action:* In the case of a deviation from a critical limit at CCPs, corrective action must occur. The HACCP plan assigns steps to ensure that no product enters commerce that is injurious to health, and that if a deviation does take place, it is corrected.[48] The processor should have a corrective action plan which can be followed for each particular deviation. If there is no corrective action plan in place that appropriate for such a deviation, then the processor must immediately segregate and hold the affected product. A review must then be carried out to determine the suitability of the affect product to be distributed, and action must be taken to ensure that no product enters commerce that is injurious to health or adulterated due to the deviation. Finally, a reassessment must be completed to determine whether the HACCP plan for the particular product requires modification.[49]

6) *Establish verification procedures:* The processor must be able to verify that the HACCP plan is adequate to ensure safety and that the plan is being appropriately implemented. This verification must include reassessment of the HACCP plan whenever changes occur that could affect the hazard analysis, or at least every year. Ongoing verification activities include a review of any consumer complaints to the producer, calibration of process-monitoring instruments, and optional end-product or in-process testing. Additionally, a review of records which document monitoring of CCPs, any corrective actions made, and the calibration of any process control instruments are commonly used as part of the verification plan.[50]

7) *Keep Records and documentation:* All records are to include the name and location of the processor or importer, the date and time of the relevant activity, a signature of the person

[48] Miget, *supra* note 25
[49] *Id.*
[50] FDA Seafood HACCP Regulations, *supra* note 30

performing the activity, and any other pertinent information. Records are to be kept for at least 1 year in the case of refrigerated products and for at least 2 years if they are frozen, preserved, or shelf-stable products. Maintaining records on computers is allowed as long as the veracity of detail and signature is maintained.[51] The seafood industry has historically had significant trouble with this record-keeping step. This is believed to be a result of considerable differences between the traditional inspection system for seafood and the modern HACCP plan. Traditionally "a plant inspection involved evaluating processing practices on the day of the 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 plan operations on the day of inspection, but also will be reviewing required records since the last inspection".[52] HACCP is much more thorough in the time covered for inspection than the traditional inspection system, which creates more of a burden to maintain consistent monitoring procedures.

Below is an example of a HACCP plan for hot smoked fish, developed by Kenneth S. Hilderbrand of the Oregon State University Sea Grant Extension Program.[53] The "monitoring" step is broken down into four sections (what/who/how/frequency), which explains the 10 steps (as opposed to 7) overall.

[51] *Id*.
[52] Miget, *supra* note 25
[53] Hilderbrand, KS. "Hot Smoked Fish Company HACCP Plan"; OSU Sea Grant Extension Program. Revised 12/30/97. Publication No. ORESU-I-97-001, Copyright Oregon Sea Grant

## HOT SMOKED FISH COMPANY HACCP PLAN

| | |
|---|---|
| **Firm Name:** Hot Smoked Fish Company, Inc. | **Product Description:** Refrigerated, vacuum-packaged, cooked, ready-to-eat, smoked fish (no mercury-containing species used - see Note #1) |
| **Firm Address:** 123 Somewhere St., Anytown USA 97365 | **Method of Storage and Distribution:** Stored and transported under refrigeration |
| | **Intended Use and Consumer:** ready to eat by general public without further cooking |

| (1) Critical Control Point (CCP) | (2) Significant Hazards(s) | (3) Critical Limits for each Preventive Measure | Monitoring | | | | (8) Corrective Actions | (9) Records | (10) Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | (4) What | (5) How | (6) Frequency | (7) Who | | | |
| Brining (see note #1) | pathogen growth during smoking and in final product | minimum brine strength and times as per process schedule | brine strength and time | salometer and in/out time | each brining batch (lot) | operator | rebrine or hold for evaluation | production log | daily record review |
| Smoking/ drying (see note #3) | pathogen growth in final product | minimum smoke-house cycle time as per process schedule | in/out process times | chart recorder | each batch | smoke-house operator | reprocess or hold for evaluation | production log and recorder charts | daily record review monthly wt. loss checks annual wps/$a_w$ checks |
| Smoking/ cooking (see note #3) | pathogen growth in final product | minimum final cook time/center temp as per process schedule | cook temperature and center temperature | chart recorder | each batch | smoke-house operator | reprocess or hold for evaluation | production log and recorder charts | daily record review, weekly recorder check |
| Cooling | pathogen growth during cooling | maximum cooler temperature | cooling room temp | chart recorder | continuous | operator | hold for evaluation/ adjust cooler temp | production log and temp recorder charts | daily record review, weekly recorder check |
| Packaging/ labeling | pathogen growth in temperature abused product | all products labeled "keep at 38°F or less" | packaging material | visual | each lot | operator | relabel | production logs | daily record reviews |
| Storage of finished product | pathogen growth | 38°F or less | cold storage | chart recorder | continuous | operator | hold for evaluation/ adjust cold room temp | production logs/ recorder charts | weekly recorder check |
| Signature of Company Official: | | | | | Date of Revision: | | | | |

## Comparison of FDA Seafood HACCP to USDA Meat and Poultry HACCP

Most studies of HACCP have focused on the USDA programs in meat and poultry. Some argue that the seafood program, administered by the FDA, is more complex, due to the greater number of products covered, the wide variety of fish species, and the complex health concerns specific to each fish and various techniques of processing. The seafood HACCP program involves a broader range of safety hazards, including pathogens, toxins, and physical contaminants.[54] The dangers with the seafood industry also appear to be relatively more significant and potentially detrimental as well. The population illness from seafood pathogens has been rising, where as the incidence of food-borne illness from pathogens associated with the consumption of meat, dairy products, and eggs has declined.[55] The Centers for Disease Control found a 47% increase in cases of *Vibrio* illness in 2004 compared to the 1996-1998 baseline data, where as there was only a 12% increase in per capita seafood consumption over this time period.[55,56]

The HACCP plan for seafood differs strikingly from the USDA version for meat and poultry, as well as from the version for low-acid canned foods. Some argue that the regulatory HACCP for low-acid canned foods are very effective in that such highly processed products can be guaranteed safe if the companies follow certain steps.[57] In an article comparing the HACCP regulations published in *Food and Drug Law Journal*, Caroline DeWall argues that "the low-acid canned foods rule is highly prescriptive, leaving little discretion to food processors as to how to implement the program. In fact, the low-acid canned foods rule is so specific that it even contains diagrams of the processing equipment, and mandates the maximum time between

[54] Alberini A, Lichtenberg E, Mancini D, & Galinato GI. Was it Something I Ate? Implementation of the FDA Seafood HACCP Program. Amer. J. Agr. Econ. 90(1) (February 2008): 28-31
[55] *Id.*
[56] Center for Disease Control and Prevention: Incidence of Foodborne Illness, 2009
[57] DeWall, Caroline Smith (1999). Delivering on HACCP's Promise to Improve Food Safety: A comparison of Three HACCP Regulations. *Food and Drug Law Journal*. Vol. 52(3). Pg 331-335.

monitoring at certain critical control points. Conversely, seafood and meat/poultry HACCP rule allow each individual processor to design the preventive controls, which are fit to each individual processing facility".[58] In her analysis, the seafood HACCP rule leaves design and implementation of HACCP plans to processors and demands little governmental oversight, and the most recent rendition of meat and poultry HACCP is similarly designed, yet involves much more intensive governmental oversight.

There are also significant differences in the use of laboratory testing for the distinct HACCP systems. Validation is testing done prior to the initial implementation of HACCP to demonstrate effectiveness of the plan in controlling food safety hazards, and verification is such testing done to continuously monitor the plan.[59] These assessments are not required with low-acid canned foods because the scientific community have already validated the process and deemed the regulation suitable to produce a safe product. DeWall argues that the similar lack of validation and verification of seafood HACCP is concerning in that "if a HACCP plan fails to address critical public health problems with the product, the only way this gap is likely to be discovered is if an outbreak occurs that is traced to the product". In DeWall's opinion, USDA implements a more sensible position regarding the use of laboratory testing in that the meat and poultry HACCP rule, validation of HACCP plans and ongoing verification by all meat and poultry plants is mandated through extensive laboratory testing.[60]

DeWall also notes other discrepancies in the regulatory enforcement of HACCP across industries. Low-acid canned foods require plant registration, filing of all HACCP plans, a "traceback" mechanism, and notification to FDA of any potentially harmful spoilage.[61] The

[58] *Id*.
[59] *Id.*
[60] *Id.*
[61] *Id.*

meat and poultry industry requires plan registration, continuous inspection by USDA, and mandatory validation/verification of HACCP plans. Seafood HACCP does not require plants to register with FDA and HACCP plans are not filed with agency or subject to frequent inspections. The significantly fewer hazards and relative simplicity of the meat and poultry industry, however, should be considered when comparing the feasibility of such testing to a highly complex trade like the seafood industry.

**Predicted Impact of HACCP in the Fish Industry**

Prior to HACCP being enforced throughout the seafood industry, there were analyses done to predict the economic gains and costs as a result of implementation. The FDA produced a impact analysis of the proposed regulations which utilized word conducted by the National Fisheries Education and Research Foundation, along with other pilot operations and experiences in Canada with their HACCP establishment. The benefits primarily considered the value of reduction in deaths and illnesses caused by seafood products. It was estimated in 1994 that about 1700-1800 cases of illness resulting from seafood are reported each year, but projected that actually number could be as high as 80,000, with a best guess of 33,000.[62] While challenging to assign exact monetary value of the potential gain in reduced seafood illnesses, the extensiveness of annual seafood illnesses was strong motivation to support HACCP.

Another benefit was considered to be the potential to speed up the flow of product through ports of entry, which would be anticipated to happen in nations where there are reciprocal agreements with the FDA. Weddig also considered the potential benefit of providing greater protection for food companies in instances of personal injury suits by utilizing the HACCP records to exhibit that adequate preventative actions were taken. A final benefit that

[62] Weddig LJ. Economics of HACCP for the Seafood Industry. Food and Drug Law Journal. (1994) Vol 49: 493-498

Weddig theorizes is increased consumer acceptance and confidence in fish products. This satisfaction could potentially lead consumers to spending the relatively high prices of seafood if quality and safety seemed assured.[63]

On the other hand, analysts also put forth several potential costs, including the price of new equipment, training, record keeping, and laboratory analyses that are all a part of the HACCP process. Another point of concern regarding imports was the potential added delay with any debates over analysis and findings or extra paperwork.[64] Importers engaging in private inspection firms in foreign travel could find the affirmative steps very burdensome, especially with required laboratory procedures, specific paperwork, or record keeping. In particular, Weddig stressed the concern of a rigorous HACCP program in causing loss of overseas sources or of the ability to fish in some areas if large amounts of catch are rejected. This could be devastating for some individual producers who would have difficulty transferring over to the stringent and demanding HACCP regulations. Ultimately, Weddig states that "whether the new system produces positive results may well depend on the level of efficiency among regulatory agencies and on their ability to avoid duplication of effort".[65]

A few years later, in 1997, Spiller published an update on the Status of Seafood HACCP in the *Food & Drug Law Journal*.[66] Here, he describes the regulations as "short, without a lot of detail, and focus[ing] on safety only". He does speak to HACCP systematizing the pre-existing responsibility of industry to produce safe food in a way that is done in a preventative manner and regularly affirmed. At this point in 1997, the FDA was engaged in several related activities, including: the development and completion of a hazards and controls guide, separate training

[63] *Id*.
[64] *Id.*
[65] *Id*.
[66] Spiller PC. Status of Seafood HACCP (1997). *Food and Drug Law Journal*. (1997) Vol 52: 327-330

courses for industry and regulators, and generating "report cards" for processors who have already implemented HACCP.[67] Several questions at this time revolved around the type of partnerships that would exist between the federal government and the states. Also, HACCP was developed in part to bypass the burden and difficulty of end-product testing. However, some argue that there is still a need for this testing, and there is debate among over how much testing would be adequate and when would it be enforced.[68] Additionally, there existed a need to clarify international equivalency agreements regarding importing seafood into the United States around the time of 1997, and a way to determine whether such equivalency exists.[69]

*Enforcement of Seafood HACCP Example:*

In 2001, there was a case of *Listeria monocytogenes* (L. mono) contaminated foods. L. mono is a bacterium and a pathogenic agent of a food-borne illness called listerios, a serious infection in humans leading to 2,500 serious illnesses and 500 deaths annually in the U.S.[70] Particular concern is also for infected women who are pregnant as well as elderly and those with weakened immune systems. On November 20, 2001, in U.S. v. Blue Ribbon Smoked Fish, Inc., Judge Sifton granted FDA's motion for summary judgment to command Blue Ribbon, a fish processor, from violating adulteration provisions of the Food, Drug and Cosmetic Act.[71] The court found that Blue Ribbon had three major violations; inadequate HACCP plans, processing of fish products in unsanitary conditions, and allowing fish products contaminated with L. mono into interstate trade.[72]

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[67] *Id*.
[68] Cormier RJ, Mallet M, Chiasson S, Magnusson H, & Valdimarsson G. Effectiveness and performance of HACCP-based programs. *Food Control* 18 (2007) 665-671
[69] Spiller, *supra* note 66; *Id.*
[70] Hutt PB, Merrill RA, Grossman LA. Food and Drug Law (University Casebook Series: Cases and Materials). Third Edition, 2007 by Foundation Pres
[71] U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition; Summary of Court Decision in United States of America, Plaintiff v. Blue Ribbon Smoked Fish, Inc. November 20, 2001
[72] *Id*.

Blue Ribbon attempted to dismiss the complaint, claiming that a new management had improved the insanitary conditions. However, the company had a lengthy history of other violations along with unsatisfactory HACCP plans. While Blue Ribbon claimed that L. mono is not an added substance and thus doesn't pose a risk to health because it only affects a narrow portion of the population, their argument was a lost cause. Instead, the court determined that L. mono is an added substance, that it is injurious to public health, and that the FDA is not required to set a tolerance level for L. mono. The court granted relief as requested by the government, recognizing that it was consonant with the legislative intent behind the Act: "[b]y keeping contaminated fish processed under conditions of filth off consumer's tables, this permanent injunction will serve that important purpose." [73]

**Positive Support for Seafood HACCP**

A paper by Cormier et al (2006) highlights several positive results of HACCP in the fish industry. The authors look specifically at 2874 samples of ready-to-eat (RTE) lobster product from Canada (collected between 1991-2001) along with 7156 samples of RTE shrimp from Iceland (collected between 1989-1999). The authors analyzed presence of particular pathogens from the samples in both locations, noting the time that HACCP-based programs were implemented in each country. Both the RTE lobster and RTE shrimp data suggested that implementation of HACCP-based programs had a net impact on their respective processes in minimizing the probability of finding *L.monocytogenes* in their RTE seafood.[74] The data also supports the consistency of such programs by showing that yearly non-compliance rates have remained unchanged without significant differences from year to year. Additionally, both sets of

[73] *Id*.
[74] Cormier, *supra* note 68

data show that with zero tolerance import regimes, any detected prevalence of *L. monocytogenes* will lead to the shipments being rejected.[75]

Alberini et al (2008) inspected 6,027 plans in the United States and its territories to examine whether HACCP and sanitation program are complements to one another, or substitutes.[76] The authors control for operational plant size by using annual sales of the plant. This study fit probit models of compliance that control for both the outcome of previous HACCP inspection and that of the previous sanitation inspection. The authors expected that "if the HACCP and sanitation standards are complements to one another, the plans in compliance with sanitation standards in previous inspections would be more likely to be in compliance with HACCP requirements in subsequent inspections, and visa-versa".[77] On the other hand, if the HACCP and sanitation programs were substitutes to one another, the authors expected that being in compliance with one program would lessen the probability of being in compliance with the other program. Such might be due to a transfer of resources from one program to the other.

The study found that the FDA appears to target plants based somewhat on the riskiness of the fish product processed at the plant, with more frequent visitations to plants that produce high-risk, (such as breaded and RTE) products. Also, FDA appeared to target plants of greater size (measured by annual sales) more frequently than smaller plants. The authors suggest this may be due to the fact that larger plants, with a higher volume of products, have potential to do significantly more public health damage than smaller ones.[78]

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[75] *Id*.
[76] Alberini, *supra* note 54
[77] *Id*.
[78] Centers for Disease Control. (2005). "Preliminary FoodNet Data on the Incidence of Infections with Pathogens Transmitted Commonly Through Food-10 sites, United States, 2004."*Morbidity and Mortality Weekly Report* 54:352-56

The study by Alberini et al. also found that a previous report of noncompliance with *sanitation* is positively associated with high cost of precautionary effort to prevent current and future noncompliance within that plant. On the other hand, a previous HACCP violation does not act as a deterrent for compliance with current and future HACCP. This indicates that a fish firms' compliance strategies and focus remain geared towards sanitation rather than HACCP compliance.[79] Furthermore, HACCP compliance did not improve compliance with sanitation standards, suggesting that the two programs are not complementary. Surprisingly, the authors found that larger plants were more likely to be out of compliance with HACCP, even though it was expected that large plants would have an easier time transitioning to HACCP than smaller plants. The authors suggest that this may be because the smaller plants only need to focus on fewer and simpler processes, thus making the transition more manageable. They also note that the data to this study is only taken from the first four years of HACCP implementation, and thus might be addressing a transition period which would thus not capture the eventual impact of HACCP implementation. [80]

**Criticisms of Seafood HACCP**

In February of 2001, Senator Tom Harkin released a report by the General Accounting Office (GAO) that specified significant deficits in the FDA's seafood-safety program.[81] This report criticized the FDA of exempting substantial sections of the seafood industry, (including warehouses, processing aboard a ship, and some processors) from regulation. Additionally, the report argued that the FDA does not inspect for some significant hazards, such as methylmercury, and that over half of the seafood industry did not have HACCP plans in place.

[79] Alberini, *surpa* note 54
[80] *Id*.
[81] GAO Gives Failing Grade to FDA Seafood HACCP Program. For immediate release, 2/13/2001. From; www.cspinet.org/new/gao_fda.html

The GAO was also displeased with the length of time it took the FDA to inform the processors of identified violations, and the lack of microbial testing use to evaluate HACCP effectiveness.[82] Overall, the report appeared to support concerns of some individuals from the Center for Science in the Public Interest, that the "FDA's seafood program is riddled with deficiencies, woefully underfunded, and provides no assurance of safety for consumers".[83]

While Cormier et al (2006) illustrated assorted positive results from HACCP-based programs, some concerns with the system were also stated. Primarily, the reliability of these HACCP systems and the assurance that the final product meets expected specifications depends upon the cumulative effectiveness of the controls and practices of the *entire* system.[84] This includes CCPs that are based on the best available scientific information and are sometimes assumed to be "fool proof" at controlling hazards resulting in zero risk, which is questionably accurate. The system also includes handling practices, sanitation cycles, monitoring procedures, corrective actions, and employees' skill level, which all have to function consistently and faultlessly to have the intended results.[85] Cormier argues that this causes some concern, and suggests that some final product monitoring would be valuable in assessing HACCP effectiveness.

Cormier et al. argues that product monitoring schemes should involve inspection that moves away from looking at specific lot problems, to monitoring the performance of the entire system controlled by HACCP based programs.[86] Such schemes should consider the number and frequency of sampled lots, and sampling should cover the start-up, operational and shut-down

[82] *Id*.
[83] *Id*.
[84] Cormier, *supra* note 68
[85] Lupin, H.M. (1999). Producing to achieve HACCP compliance of fishery and aquaculture products for export. *Food Control*, 10, 311-314.
[86] Cormier, *supra* note 68

phase of the seafood processing cycle. The authors argue that it is also important that the number of lots sampled is adequate to ensure statistical comparison of HACCP-based performance from year to year. This paper also addresses the continued concern that HACCP programs are not yet homogeneous between trading partners, and argues that "equivalence in food safety systems should focus on achieving similar levels of protection against fish-borne health hazards and quality defects by whatever means of control and management processes".[87]

**Impact of HACCP on Fish Trade with Other Countries**

A study by Anders & Caswell (2009) found that mandatory HACCP implementation had an overall negative effect on imports into the United States. Overall, HACCP implementation has reduced trade flows across all countries over the time period of 1990-2004.[88] This finding accounted for other seafood trade factors, such as time, United States GDP, distance, and export orientation. The data was taken from the top 33 exporting countries to the US, where 24 were developing countries, and 9 were developed countries. Developing and developed countries had different trends, and thus an individual country-level analysis perspective may be more useful than a general picture of how HACCP has affected imports into the US. Developed countries appeared to gain under HACCP implementation, yet developing countries both gained and suffered under HACCP; results varied among countries.

The data suggested that "among developing countries increased standards act as a catalyst for larger, more established exporting countries and as a barrier for smaller exporters".[89] Thus, neither a "standards as barriers" nor a "standards as catalysts" hypothesis fits developing countries as a whole; size should be taken into consideration. Such findings imply a greater need

[87] *Id.*
[88] Anders SM & Caswell JA. Standards as Barriers Versus Standards as Catalysts: Assessing the Impact of HACCP Implementation on U.S. Seafood Imports. *Amer.J. Agr. Econ*. 91(2) (May 2009):310-321
[89] *Id*.

to obtain more detailed economic modeling and analysis of the trade effects of increased food safety, which would support measurements of the welfare effects of such food safety standards for developing countries and their individual challenges.[90]

*Case Study – Africa:*

Africa contributes about 5.8 million metric tons each year to the world harvest of aquatic organisms; roughly the same amount as the United States.[91] Many African countries depend on fishery activities and products as a source of protein, employment, and foreign exchange earnings. In countries such as Angola and the Congo, fish makes up about 38-58% of the total animal protein. Soon after the HACCP approach was first being introduced in the major fish markets of the US and UK in the 1980s, the *Codex Alimentarius Commission* (CAC) gave the guidelines international significance. Producers in Africa recognized at this time that traditional methods of marketing and distribution of fish were significantly out of line with such quality assurance programs, and significant efforts would be needed to adapt to the new and stricter safety-improvement in quality assurance programs based on HACCP for fishery products.[92] The authorities of the US and UK announced that by 1998, fish imports would only be permitted from countries or companies that have complied with such legislation.

The African continent faced several constraints in applying the new regulations. Many African countries lacked quality control laboratories or required service equipment, and staff were poorly pained and many illiterate. It was clear that the changeover period would be difficult, and would require technical assistance from international organizations or donors. At the industry level, around 50% of the plans were closed after implementation of the National

[90] *Id.*
[91] Tall, Amadou. "Improvement in Quality Assurance Systems Based on HACCP Application". Director of INFOPECHE. From; http://www.unctad.org/infocomm/comm_docs/docs/projectp/docsgamb/gambiahaccp.pdf
[92] *Id*.

Fish Inspection Program.[93] However, many African countries received financial and technical assistance in implementation HACCP from international organizations, such as FAO, UNIDO, and EU. By 1996, over 700 African fish inspectors and quality control supervisors had been trained.[94] Consequently, many African fish producing countries have been approved by the EU to export its products, which has been crucial to their economy.

While a challenge for many African countries to first establish the means of HACCP-like regulations, doing so has assured the quality and safety of their products which is a significant plus in the long-run.[95] Currently, many African countries still need HACCP training, and will depend on donor countries and international assistance to do so. Investing in these countries is certainly worthwhile to fully utilize their available resources; as fish demand and prices are increasing, investments in this area will generate profits. There has been focus on support with HACCP application in many African countries, but future support is needed to focus on verification, auditing of HACCP systems, and assessing the costs of quality.[96] Overall, this case scenario has shown that with support, developing countries can adapt to the quality assurance program based on HACCP for fishery products to be in compliance with EU and US directives, which is a smart investment for the international fish industry.

**Where We Stand with Fish HACCP Today and Looking Forward**

It has been proposed by some that HACCP regulations be applied to retail operations, such as restaurants, to assure safety and quality of multiple food item preparation and delivery processes. Dr. Peter Snyder (2000) suggests that the recipe be the control document for HACCP in retail food operations, and illustrates how the 7 principles of HACCP can be adapted to a

[93] *Id*.
[94] *Id*.
[95] Donovan JA, Caswell J, and Salay E. (2001). "Effects of Sticter Foreign Regulations on Food Safety Levels in Developing Countries: A study of Brazil." *Review of Agricultural Economics* 23:163-75
[96] Tall, *supra* note 93

recipe flow analysis. He first condenses the 7-principles into 5 where the focus lies on microbiological controls. A major obstacle in retail food operations for monitoring procedures is the lack of pH meters, adequate thermometers, or other microbiology tests on foods to ensure that microorganisms are at a safe level.[97]

The International Association of Food Protection (IAFP) created a development group for Retail Food Quality and Safety whose mission is to develop scientific HACCP-based critical control practices for retail food operations which could be similarly used for home cooking. [98] Initially, it seems as though this would be a daunting task given the millions of different types of recipes and preparations, however Snyder argues that there are multiple processes which can be categorized into a few groups (thick foods, thin foods, beverages, cold combinations, hot combinations, candy, etc.). Subsequent HACCP plans could then be written for those select categories, and worked into a recipe flow analysis that could be used for cooking procedures. He even goes to project a time "when it will be possible to type a recipe into a computer and have the computer validate that the microbiological hazards are controlled, provided the food preparer follows the specified time and temperature specifications".[99] I have yet to find whether we have made any progress in this concept. The idea of having a HACCP based model in restaurants would be advantageous in creating industry self-control, reducing the need for regulatory inspections because chefs would follow scientifically proven procedures and controls.[100]

While in place since the late 1990s, seafood HACCP regulations are still developing and evolving. The FDA generates a biannual report which provides compliance levels, which is

[97] Snyder, P. (2000). HACCP in Retail Operations: Integrating FDA Fisheries, USDA, FDA Industrial, and FDA Retail HACCP into one set of Retail Food Industry Self-Control Requirements. *Hospitality Institute of Technology and Management*. Accepted for Publication September 5, 2000.
[98] International Association for Food Protection (IAFP), Committees and Professional Development Groups; Retail Food Safety and Quality Professional Development Group. Committee Minutes 2009
[99] Snyder, *supra* note 99
[100] *Id*.

indicate there is always room for improvement. The most recent evaluation covered the status of domestic seafood processors and importers and international seafood processors in Fiscal Years 2004 and 2005 in operating preventive controls under HACCP. On the domestic side, the evaluation reflects the implementation of seafood HACCP programs by processors. The data within this report is based on observations by FDA and state inspectors during regulatory inspections. On the international side, the report reviews the status of HACCP implementation (FY 2004-2005) by 153 processors in 20 countries that were visited by FDA investigators. It also includes a summary of the implementation of seafood HACCP controls by U.S. importers. Firms are classified by FDA as "no action indicated" (NAI), "voluntary action indicated" (VAI) if the firm is determined to be "in compliance". If the firm is not deemed to be in compliance, it is classified as "official action indicated" (OAI).

Focusing on domestic compliance rates during the first four years of HACCP implementation, the percentage of NAI firms increased each year and the percentage of VAI firms decreased, which FDA reported as indicating that many of the VAI firms voluntarily corrected their deficiencies.[101] For the first three years of the program, the percentages of VAI and NAI have fluctuated relative to one another, with the most recent report in 2005 as being approximately equal percentages. The OAI classification has been the smallest category with each biannual review, but its size increased in each of the first four years as some firms failed the opportunity to make needed corrections. [102] There was a significant drop in the 2003-2004 review from the previous 3 years in percentage of OAI firms, which implies that some OAI firms have corrected their deficiencies either as a result of past regulatory action or because they otherwise recognized the need to do so. This decrease in numbers continued with this most

[101] FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005. Domestic Industry Progress "Compliance Rate" (Last updated 11/30/2009)
[102] *Id*.

recent report through 2005. The overall "compliance" rate, including both NAI and VAI classifications, for FY 2005 was about 91 percent.[103] Many in the seafood industry feel that the greatest impact that seafood HACCP regulations has had is the generation of knowledge and awareness regarding safety issues for seafood. HACCP also offers a regulated way in which to "talk" about these health concerns of specific fish products. Within the seafood industry, both domestically and internationally, there has been a significant increase in the understanding of such issues, particularly concerning the complex safety risks of a broad range of fish species and methods of preparation.[104]

Seafood HACCP has also improved the safety standards of fish around the world. While affecting some countries more than others due to the difficulty of implementation, it appears that with enough time and support, a country can adapt to such required regulations. This not only ensures the economic stability of the fish industry within a particular country, but also increases the standard and quality of the seafood by default. The international component is very important to seafood products, and the US relies on trade with many other countries. HACCP has been translated into many languages for use around the world.

The certainty that practices are being followed as indicated varies from country to country, and consistency of international standards is an area that many within HACCP are trying to work towards achieving. The most recent FDA evaluation of seafood HACCP indicates that several elements of this program are significantly less successfully conducted in foreign countries compared with the United States. The identification of significant Hazards, Critical Control Points, Critical Limits, Monitoring Procedures, and Corrective Actions averaged 15

[103] *Id.*
[104] Gall, *supra* note 36

percentage points lower for foreign processors from those of U.S. processors.[105] The FDA suggests that this may be due to "some foreign processors and local competent authorities failing to understand or be aware of FDA's safety recommendations. It may also be in response to FDA's targeting of suspected non-compliant foreign processors for inspection".[106] It is difficult to identify the root of this disparity with certainty. FDA plans to continue to "target countries and processors with identified problems on future inspection trips. The above caveat notwithstanding, earlier evaluations suggested that importers generally improved between FY1998 and 2001 in their preparation of written product specifications and written 'affirmative steps'."[107] However there has been little progress made after this year with importers actually implementing and documenting sufficient affirmative steps.

There will always be challenges to seafood HACCP, and this paper has touched on many criticisms of these regulations. However, one must consider to extreme complexity of safety issues related to fish consumption, and the amount of regulatory manpower available. Fish are exposed to many uncontrollable and fluctuating risks in their wild environment, and there is only so much that the fish industry can feasibility do to control these risks. HACCP is an excellent way to assure that all responsible parties of the fish industry do what is possible to control safety risk in fish, and prevent any fish product that is hazardous to human health from entering commerce. As long as fish product is used and consumed in the same way, there will always be some risk of illness with consumption, particularly when eaten raw or in certain species such as shellfish and mollusks.[108]

[105] FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005
[106] *Id*.
[107] *Id*.
[108] *Id*.

The HACCP guide is currently in review, and individuals working in the seafood industry are anticipating some significant changes and modifications to the guide. When these updates do occur, there will be a demand to have everyone updated on what the changes are, and a need for a new generation of workers to be trained. Some industries have been putting of training new workers until this new guide is released.[109] The FDA makes several recommendations in their most recent biennial evaluation of the Seafood HACCP Program, including: continue to prioritize all processors of high risk potential fishery products for annual inspection, increase the inspectional priority of processors and importers of aquaculture products, increase the number of importer inspections to reflect a more accurate representation of the industry size, implement outreach programs to educate importers about their responsibilities, implement outreach programs for foreign industry groups to provide guidance, along with several others.[110]

Ultimately, seafood HACPP has made the industry much more aware and proactive about risks that consumption of seafood products possess. The absolute implications of such regulations may yet be determined, especially on an international scale. As consumers are becoming increasingly aware of the both the dangers (e.g. methylmercury) and benefits (e.g. omega-3 fatty acids) that consumption of fish can bring to human health, the industry will be under increasing pressure to guarantee that fish products are safe to eat. Scientific knowledge of new environmental toxins that may affect our fish supply will be continuously evolving, and HACCP regulations and training will have to simultaneously adapt. HACCP has already made significant progress in transforming an industry that is as old as human civilization, to provide confidence that consumption of seafood is as safe as possible.

[109] Gall, *supra* note 40
[110] FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2004/2005, *supra* note 105