Safe, wholesome seafood is one of Virginia's most valuable commodities. The Commonwealth is the nation's third largest producer of seafood, bringing in more than 440 million pounds per year. Poorly handled seafood is not only an economic loss, but also may create a hazard for consumers. To properly mitigate these hazards (which could be caused by biological, chemical, or physical contaminants), seafood processing and distribution companies must ensure that key personnel know the potential risks and the steps that can be taken to control them. Seafood in the United States is regulated by the U.S. Food and Drug Administration (FDA). FDA announced in December of 1995 that seafood firms would be subject – effective in one year – to a new set of regulations, based on the principles of Hazard Analysis and Critical Control Points (HACCP).

Impact of the HACCP Regulation

The new regulation was enacted by FDA in an effort to simultaneously increase the safety of the food supply while reducing the number of FDA inspectors and inspections of seafood processing and shipping establishments. The HACCP concept was developed in the 1960s by Pillsbury Corporation when NASA needed to be sure that foods...
stocked for space missions could be certified as safe. Until HACCP, food products were tested for safety only after they were handled and processed. This testing process resulted in the destruction of large volumes of the end product without the benefit of assurance that the foods were free of safety hazards.

The HACCP paradigm was preventive, designed to first identify steps in processing that carried a potential hazard (the Hazard Analysis), and then define precisely how those hazards could be mitigated (establishing the Critical Control Points). By establishing this stepwise analysis and management plan, potential food safety problems could be avoided before they occurred.

Prior to 1995, the HACCP concept was largely unknown in the fish and shellfish industries. Commonly, seafood packing houses and shipping companies had operated in the same way for generations, and many of the standard operating procedures were dictated by tradition and business sense, instead of by regulation. But under HACCP, each producer of fish and shellfish products needed to develop and implement a HACCP plan before December 1996, if one or more of the identified hazards existed. The regulation further specified that certain seafood processing jobs be performed by personnel specifically trained in HACCP.

Clearly this ruling left Virginia seafood processors and distributors, as well as their counterparts all over the country, in a very difficult situation. Processors faced a steep learning curve, substantial unexpected expenses for monitoring equipment and hazard control, and dire consequences if the regulation's requirements were not met. Watermen, seafood processors, and distributors alike called for assistance in managing this challenge.

**Virginia Sea Grant Takes Action**

Virginia Sea Grant was one of six Sea Grant College Programs that formed the National Seafood HACCP Alliance to provide education and training for industry, educators, and regulators and ensure satisfactory compliance with the FDA HACCP regulation. The alliance was formed with the support of Sea Grant directors in Virginia, North Carolina, Louisiana, California, Florida, and Alaska.

Almost none of the fish and shellfish firms affected by the proposed rule had the personnel to successfully comply with the components of the HACCP regulation. In addition, many state and federal food regulators were unfamiliar with the nature of inspections based on the HACCP principle. To further complicate the issue, educational materials and knowledgeable instructors were not available. It appeared likely that when the HACCP regulation became law on Dec. 18, 1996, almost all products introduced into the marketplace would by statute be designated as adulterated, meaning that they could not be sold. A finding of non-compliance with the HACCP regulation would be financially
devastating to most fish and shellfish farms.

The Seafood HACCP Alliance was formed as a collaborative effort among industry, academia, and government. The Alliance’s primary objective was to develop and implement a comprehensive educational program that would meet the needs of industry, educators, and regulators so that full and correct compliance would be possible by the regulation’s implementation date.

The Alliance faced a formidable task in achieving its goal. Educational materials needed to be developed, a curriculum defined, a cadre of educators trained, and a number of courses offered to national and international participants—all within a relatively short time. Complicating the effort were the multiple product safety issues specific to different species, geographic regions, and product types. The talent required to successfully address such a national outreach task was widespread. Sea Grant, possessing the necessary resources and having established the necessary bridges between industry and regulatory agencies, was the one agency able to assume such a massive undertaking.

**Forming the Alliance**

The Alliance met regularly from 1995-1999, and established an online discussion group to facilitate the free exchange of ideas and information on issues related to seafood safety. These discussions enabled the Alliance to develop a compendium of science-based methods; list key research needs, and enhance public sector awareness of the issues that needed to be faced. The ultimate goal was to ensure that each seafood-processing establishment in the U.S. had the knowledge and support necessary to craft and implement its own HACCP plan, and to stay in compliance with the regulation.

It was also critical that the education program being developed by the National Seafood HACCP Alliance be recognized by all state and federal regulatory agencies, and enlist the support of AFDO, the Association of Food and Drug Officials of the U.S.

**Teachers and Teaching Materials**

In response to these challenges, the Seafood HACCP Alliance produced HACCP: Hazard Analysis and Critical Control Point Training Curriculum. This 276-page manual complemented the U.S. Food and Drug Administration’s Fish and Fishery Products Hazard and Control Guide to make a two-volume set that outlined all the knowledge necessary to evaluate procedures, identify hazards, and write a control plan that was in compliance with the HACCP regulation.

The primary authors of this manual also undertook the task of calling together and providing training for a cadre of HACCP instructors. These “train-the-trainer” courses, held during 1996, produced a fully approved group of instructors to handle the expanding roster of course offerings.

**The HACCP Courses**

Within three years of the start of the program, educational materials were developed, a cadre of professionals trained, a certification program established, and a system implemented to provide additional training ensuring that all firms had the necessary information to become and remain compliant with the regulation.

Since the outreach program was initiated, 569 AFDO-recognized HACCP training courses have certified more than 13,000 processors, educators, and regulators in the U.S. and internationally. Also, 10 ISSC (Interstate Seafood Sanitation Conference) courses have been offered to nearly 300 shellfish dealers.
Long Term Impact

As a result of the cooperative program established between state food regulators and Virginia Sea Grant, none of the state’s more than 500 fishing, processing, and distribution firms has been prosecuted for failing to comply with the HACCP regulation. Hundreds of firms have continued normal business operations, thousands of individuals have retained their jobs, and millions of dollars of food product has not been declared as adulterated.

Following initiation of the FDA-Sea Grant HACCP outreach program, the FDA has reported a high level of compliance with the regulation. Firms reported as having unacceptable HACCP plans by the FDA have been cited only for minor errors, such as failing to date and sign forms, failing to fully complete forms, or failing to successfully adhere to the SSOP (Sanitation Standard Operating Procedures) requirements of the regulation. Very few compliance failures have been judged to compromise product safety or result in an unacceptable health hazard.

New Directions

The HACCP Alliance has prepared a second national outreach program to provide information and guidance on the SSOP requirements of the HACCP regulation. This program is similar to the first in that a curriculum and training materials have been developed, train-the-trainer courses offered, a certification system established, and courses offered on the local level as required. To date, 71 courses have been offered across the nation, reaching more than 1,100 key players in the handling of the U.S. food supply.

A Model for Success

The Seafood HACCP Alliance outreach effort has been cited by officials at the FDA as the best cooperative venture between their agency and universities. The National Seafood HACCP Alliance also received the Vice President Al Gore National Performance Review Hammer Award in 1997, and a USDA Group Honor Award in 1989. Dr. George J. Flick Jr., Virginia Sea Grant’s project leader in Seafood HACCP Alliance collaboration, was awarded the USDA’s Award for Superior Service in 1998, partially as a result of his participation in the efforts of the National Seafood HACCP Alliance.

Other industry groups, noting the success of the National Seafood HACCP Alliance, have sought to use it as a model for their own efforts to incorporate HACCP principles in their manufacturing and processing operations. Virginia Sea Grant has cooperated with the FDA Center for Devices and Radiological Health to develop a HACCP based quality assurance and safety program for medical device manufacturers. A curriculum has been developed with accompanying educational materials, a certification system established, and courses offered nationwide.

Sea Grant efforts to advance the agenda of the National Seafood HACCP Alliance have provided lasting benefits to the seafood industry in the Commonwealth of Virginia and beyond. The implementation of seafood HACCP has benefited everyone involved, giving harvesters and producers ways to mitigate hazards, streamlining the inspection process and bringing safer seafood to our marketplace.
Accomplishments and Significant Findings

Forming the Alliance

✰ Positive networking between industry, academia and government to develop a compendium of science-based control methods, list research needs, and enhance public sector awareness of the issues that needed to be faced

✰ Development and implementation of a nationally-recognized educational curriculum

Teachers and Teaching Materials

✰ Cadre of approved instructors offered courses in convenient locations across the country and in a number of locations abroad

✰ HACCP manual and related materials designed to complement the FDA Fish and Fishery Products Hazard and Control Guide

The HACCP Courses

✰ A total of 579 courses offered, training more than 13,500 individuals in the Commercial Fish and Shellfish Industries

✰ Specialized courses offered to niche groups within the seafood industry (e.g., shellfish shippers), regulatory agencies, and Fortune 500 corporations

New Directions

✰ Related materials produced to assist in compliance with the SSOP portion of the HACCP regulation, the area where most substantive problems were encountered

✰ Since the inception of the SSOP curriculum, 71 courses have been offered, training more than 1,100 people

A Model for Success

✰ National Seafood HACCP Alliance awarded the Vice-President Al Gore “Hammer Award” for its outstanding ranking in the National Performance Review, 1997

✰ George J. Flick, Jr., Virginia Sea Grant’s project leader in Seafood HACCP Alliance collaboration, awarded the USDA Award for Superior Service, 1998

✰ National Seafood HACCP Alliance awarded the USDA Group Honor Award, 1999

✰ Medical device manufacturers use the Seafood HACCP Alliance Curriculum as a model for their own HACCP implementation programs

Long-term Impact

✰ Improved seafood quality with fewer inspectors

✰ Continued economic viability of the fish and shellfish industries, and production of safer, better products
Project Team

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Project Partners

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Hyman, Phelps & McNamara, P.C.
Interstate Shellfish Sanitation Conference (ISSC)
National Fisheries Institute, Inc. (NFI)
National Food Processors Association (NFPFA)
National Marine Fisheries Service (NMFS)
U.S. Department of Agriculture - Cooperative State Research
Education and Extension Service (USDA-CSREES)
U.S. Food and Drug Administration (FDA)
U.S. Trout Farmers Association (USTFA)
Virginia Department of Health (VDH)
Virginia Department of Agriculture and Consumer Services (VDACS)
Virginia Seafood Council

Sea Grant Programs at:
University of California
North Carolina State University
Louisiana State University
University of Alaska
University of Florida

Cooperative Extension Service Programs at:
Kansas State University
Utah State University
Colorado State University
Texas A&M University
Penn State University
University of Maine

For Additional Information

See the Virginia Sea Grant web site at
http://www.virginia.edu/virginia-sea-grant
and the Commercial Fish and Shellfish Technologies web site at
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