

**FINAL REPORT**

**PROJECT TITLE: "Molluscan Shellfish - Quality Control and Education"**

**PRINCIPAL INVESTIGATOR: Judy L. Jamison  
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Foundation, Inc.**

**GULF & SOUTH ATLANTIC FISHERIES DEVELOPMENT FOUNDATION, INC.  
COOPERATIVE AGREEMENT NO. NA90AA-H-SK042  
CONTRACT NUMBERS: 40-18-46000/16000  
AWARD PERIOD 08/01/90 THROUGH 07/31/91**



\* A report by the Gulf & South Atlantic Fisheries Development Foundation, Inc. to the National Oceanic and Atmospheric Administration pursuant to NOAA Award No. NA90AA-H-SK042. The views expressed herein are those of the author and do not necessarily reflect the views of NOAA or any of its sub-agencies.

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Grant No. NA90AA-H-SK042

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Project Title: "Molluscan Shellfish - Quality Control and Education"

Grantee: Gulf & South Atlantic Fisheries Development Foundation, Inc.

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### I. Executive Summary

The goal of this project was to reduce public health risks from molluscan shellfish sold by retail stores, and to improve the quality of these products by creating an easily understood training tool to introduce retailers to the HACCP concept for seafood inspection. In achieving this goal the investigators developed two videos, aimed at retailers and wholesalers respectively, to introduce the HACCP concept as applied to molluscan shellfish, and developed an accompanying manual to detail the methods for establishing and maintaining a HACCP program for molluscan shellfish. These videos orient molluscan shellfish wholesalers and retailers to the new FDA/US Department of Commerce Hazard Analysis Critical Control Point (HACCP) Seafood Inspection. These videos are currently being used nation-wide by Federal and State regulatory agencies as well as all other interested parties.

### II. Introduction

Molluscan shellfish, and in particular, oysters, clams and mussels, pose unique public health problems because they are raised in uncontrolled environments, thus making them subject to contamination from viruses, pathogenic micro-organisms, or toxins present in growing areas. The potential health risk is higher than with other seafoods because these products are often consumed raw, or are not cooked long enough. Consequently, shellfish require close control during all phases of harvesting, processing, distribution, and marketing to ensure that they are taken from approved growing areas, and that they are processed, distributed, and marketed under hygienic conditions, with proper use of refrigeration and handling techniques. Therefore rigid sanitary control

from the growing waters to consumer sales has been proposed to improve shellfish safety. HACCP (Hazard Analysis Critical Control Point) is a concept of controlling hazards through a process of defining what hazards may exist and monitoring points to control or prevent their occurrence.

The HACCP system has been in use in various industries for almost two decades. It is currently becoming more prevalent in the food industry, and is the subject of intense interest in the areas of seafood inspection and handling. The system, based on the analysis of risks present at each step of the food distribution chain, from harvest to table, establishes control parameters, actions to be taken, and record keeping practices to be followed, creating an easily maintained system of observation, action, and an accurate paper trail.

How HACCP can improve molluscan shellfish safety is now under rigorous study. Any proposal to improve public health safeguards for molluscan shellfish must recognize that the States and industry share responsibility for product safety. This is a significant difference from other food industries in that the principle critical control point (i.e. harvest water testing, records, and management) is under State or Federal control rather than directly under industry control.

The purpose of this project was to aid in reducing public health risks from eating molluscan shellfish sold by retail stores by introducing the HACCP concept of molluscan seafood inspection to seafood wholesalers and retailers.

### III. Purpose

The problem addressed by this project is the danger posed to consumers by raw or undercooked molluscan shellfish products because these products are subject to contamination from viruses, pathogenic microorganisms, or toxins present in growing areas. Raw molluscan shellfish products have long been considered a delicacy in the U.S. However, because shellfish such as oysters, clams, and mussels are filter feeders that exist in estuarine environments, they are subject to the multitude of negative effects of pollution resulting from increased urbanization of these areas. Since molluscan shellfish are filter feeders, they take in virtually any material that is suspended in the water column. Therefore, pollutants, biological pathogens, and heavy metals are ingested and potentially incorporated into tissues of these organisms, thus increasing the potential health risk to shellfish consumers. This problem is exacerbated by the fact that, with increasing proportions of the U.S. population residing in coastal areas, demand for shellfish

products has increased concurrent with increasing health risks posed by eating these products raw.

Consequent to increasing health risks from eating raw shellfish products, as evidenced by increasing numbers of reported illnesses from ingestion of these products, is a potential reduction in demand for raw shellfish products by consumers who are fearful of being made ill. As a result, it is critical that a process be developed that builds confidence in the overall quality and wholesomeness of shellfish products from the grower/harvester level through the consumer level. By addressing problems related to the quality of molluscan shellfish products, it is believed that ultimate health risks to the consumers eating these products will thereby be reduced.

The objective of this project was to promote the use of HACCP based quality assurance/food protection to industry, government, academia, and consumers, as a means of significantly reducing the health risks associated with eating raw molluscan shellfish in the United States.

#### IV. Approach

This project developed a video/manual kit to provide an introduction to the molluscan shellfish HACCP system. This kit addresses the links in the chain from harvest to consumer identifying critical control points, parameters of control, actions to be taken and record keeping techniques. Project tasks included the following:

- Task 1: Survey and analysis of the relevant safety and hygienic problems in harvesting, handling, distribution and marketing of molluscan shellfish. Through a systematic survey of industry, regulatory and advisory agencies, critical control points specific to molluscan shellfish were identified, and measures necessary for their control were established.
- Task 2: Development of a generic HACCP program for seafood. A HACCP program addressing those critical control points peculiar to the seafood industry was developed. This included harvesting, distribution, handling, storage and marketing.
- Task 3: Interpretation of the generic program to a HACCP program for molluscan shellfish and development of a video script and manual text. In cooperation with the Interstate Shellfish Sanitation Conference (ISSC) and the National

Oceanic and Atmospheric Administration (NOAA), the generic HACCP system was applied to the molluscan shellfish model. This model and the methods for development, maintenance, and record keeping was used to create a video script and manual text.

Task 4: Production of the finished kit.

The Food Marketing Institute (FMI) carried out this project under the direction of the Gulf & South Atlantic Fisheries Development Foundation, Inc. FMI is uniquely qualified to carry out this program because of its expertise in the food industry. FMI is a non-profit organization that conducts programs in research, education, and public affairs on behalf of its fifteen hundred members. FMI's domestic member companies operate more than 17,000 retail food stores which range from small independent supermarket operators to large regional and national food chains. It has an on-going seafood program and is in a position to expand this program to carry out this project. The Gulf & South Atlantic Fisheries Development Foundation, Inc. is a non-profit research and education foundation that is owned by the commercial fishing industry from Virginia to Texas. Its members consist of representatives of virtually all commercial fishermen and processors organizations and associations in this region.

V. Findings

The projects actual accomplishments and findings are listed as follows:

1. The advantages of the HACCP inspection approach to minimizing food born disease in molluscan shellfish was documented in video form.
2. An educational video was developed to be used to introduce the HACCP inspection approach to be used throughout the seafood industry.
3. Wholesalers and retailers were alerted to the dangers of contamination inherent in handling molluscan shellfish, and guidelines were recommended to wholesalers and retailers on reducing these dangers.
4. Ground work was laid for an educational program to be used to introduce HACCP seafood inspection for molluscan shellfish.
5. Educational materials were developed including videos for

wholesalers and retailers, and an information brochure to accompany the videos.

6. The final product was reviewed with government agencies, trade associations, and other interested parties. Three copies of each video (one each for wholesalers and retailers), and three copies of the accompanying brochure are included with this final report.

No significant problems developed that impeded this project or produced less than satisfactory results.

## VI. Evaluation

Stated briefly, the original project goals and objectives were as follows:

The goal of this project was to create an easily understood training tool to introduce the retailer to the HACCP concept as it is applied to molluscan shellfish in order to reduce public health risks from molluscan shellfish sold by retail stores, and to improve the quality of this product. Specific objectives include:

- \* Development of videos, aimed at wholesalers and retailers, to introduce the HACCP concept as applied to molluscan shellfish.
- \* Development of an accompanying brochure to spell out the methods for establishing and maintaining a HACCP program for molluscan shellfish.

The project developed a video/brochure kit to provide an introduction to the molluscan shellfish HACCP system. This addresses the links in the chain from harvest to consumer, identifying critical control points, parameters of control, actions to be taken, and record keeping techniques. Tasks included the following:

- \* Survey and analysis of relevant safety and hygienic problems in harvesting, handling, distribution and marketing of molluscan shellfish.
- \* Development of specifications and procedures within a generic HACCP program for seafood that can be used by the retail industry to ensure that safe and high quality products are sold to the consumer.

FINAL PROGRESS REPORT

Cooperative Agreement No. NA90AA-H-SK042

Contract No. 40-18-46000/16000

Page 6

- \* In cooperation with the Interstate Shellfish Sanitation Conference, interpretation of the generic program to a HACCP program for molluscan shellfish and translation of the molluscan shellfish HACCP program to a video and brochure format.

- \* Production of the video/brochure kit.

- \* Preparation of final report.

The goals of this project were measurable in terms of the positive reception to the video/brochure kit by the seafood industry. No significant modifications were made to the project goals and objectives. All of the goals and objectives were achieved as evidenced by the positive response received to the HACCP educational video/brochure kit.

The specific product resulting from this project was the video/brochure of HACCP seafood education introduction kit. This project is an integral part of the overall plan of the U.S.F.D.A. and the U.S. Department of Commerce new seafood inspection system. The presentation centers on understanding HACCP and uses molluscan shellfish as the example. The project divides the HACCP model into two distinct responsibilities: (1) the distributor/supplier, and (2) the retailer. The video also sets down the proper procedure for developing a HACCP compliance system.

The goal of this project has been accomplished as evidenced by the video being utilized by industry, academia, and government, with extremely high acceptance. The philosophy and content of the educational material parallels the specific concepts and goals of both U.S.F.D.A., U.S. Department of Commerce, and the National Marine Fisheries Service. This program is currently available to the industry and has been used to illustrate and assist in the development of HACCP models with the new FDA/NMFS seafood initiative. As a result, this project served a very important need of the industry; to reduce the dangers inherent in handling of molluscan shellfish products, and the industry has had a high degree of access to the product through use of the video/brochure kit. Since HACCP seafood inspection is the subject of intense interest in the areas of seafood inspection and handling it is highly likely that this project will be used to satisfy the fishing industry's need to reduce risks associated with the processing and consumption of molluscan shellfish. As a result, the projects results are highly likely to be used by the industry in the future, and in fact are already being used by the industry to a high degree.

The value of this project is the development of a better inspection system for the fishing industry, thus helping to ensure that safe, wholesome, high quality molluscan shellfish products enter the

marketplace. The consensus of both industry and government is that the HACCP based inspection program will benefit the seafood industry both in terms of production of a high quality product, and in terms of lower inspection costs. Because of the magnitude of this program in terms of cooperation between Federal, State, academic and industry interests, Federal assistance in producing acceptance of new HACCP inspection program is critical. In addition Federal assistance was needed in the educational program that was designed to show coordination and cooperation of both industry and government.

## VII. Conclusion

Information and education is essential in the successful implementation of the HACCP concept for the inspection of molluscan shellfish and for seafood in general. Through this information/education program, wholesalers and retailers may focus on particular portions of their processing procedures to reduce the likelihood of contamination without feeling compelled to learn about topics that are peripheral to their operations. Therefore monitoring procedures are focussed on critical control points in the processing of molluscan shellfish, rather than on teaching basic bacteriology and other topics that are not necessarily pertinent to the processing operation.

HACCP is the preeminent seafood quality enhancement/inspection program for the improvement of food safety techniques. Quality control and food safety programs must depart from ineffective and inefficient elements and traditional food protection activities. Leaders in these fields must stimulate universal acceptance of the HACCP system and guide its implementation in all food operations.

Much work needs to be done in implementing HACCP systems including changing the perception of seafood processors that HACCP will impose unnecessary costs and increased paper work, and ensuring that the information/education program translates to real changes in processing procedures. However, the project was successful in making a major step toward solving the problem of minimizing the risk to consumers from seafood contamination. Further work will need to be done to aid in implementing HACCP programs, and in improving consumer confidence in seafood products, especially raw molluscan shellfish products, once HACCP programs are implemented.



FINAL PROGRESS REPORT  
Cooperative Agreement No. NA90AA-H-SK042  
Contract No. 40-18-46000/16000  
Page 8

July 2 Jamison  
Signature of Principal Investigator

10/31/91  
Date

Peter R. Hoar  
Peter R. Hoar, Project Director

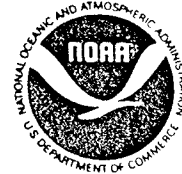
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**FINAL REPORT**

**PROJECT TITLE: "Molluscan Shellfish - Quality Control and Education"**

**PRINCIPAL INVESTIGATOR: Dr. John Farquhar  
Food Marketing Institute**

**GULF & SOUTH ATLANTIC FISHERIES DEVELOPMENT FOUNDATION, INC.  
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## I. Executive Summary

### A. A brief and succinct for final report

Two videos plus accompanying educational materials were produced. These videos are the basic orientation to the new FDA/U.S. Dept. of Commerce Hazardous Analysis Critical Control Seafood Inspection. These videos are currently being used nationwide by Federal and State regulatory agencies as well as all interested parties. The production and finalization of this work was done in cooperation with various governmental agencies.

## II. Introduction

Molluscan shellfish, most frequently oysters, clams and mussels, pose unique public health problems. They are frequently consumed whole and raw. The National Shellfish Sanitation Program (NSSP) is a cooperative federal/state/industry partnership which produces uniform guidance for subsequent state codification. Rigid sanitary control from the growing waters through point of consumer sales is proposed to improve shellfish safety. HACCP (Hazard Analysis Critical Control Point) is the concept of controlling hazards through a process of defining what hazards may exist and monitoring points to control or prevent their occurrence.

How HACCP can improve molluscan shellfish safety is now under rigorous study. This report will briefly review current control practices of the NSSP to suggest how HACCP video may be used to promote shellfish safety. Any proposal to improve public health safeguards for molluscan shellfish must recognize that the states and industry share responsibilities for product safety. This is a significant difference from other food industries in that the principal critical control point (i.e., harvest water testing, records, and management) is under state (or federal) control, rather than directly under industry control.

Within the content of the video it points out that states are responsible for: 1) ascertaining the safety of its harvesting waters and 2) assuring that harvesting takes place only in properly classified and approved areas. Industry assumes responsibility for using resources only from approved sources and in complying with prescribed processing, handling and record keeping requirements to maintain product safety and identity. An understanding of existing public health controls, responsibilities, and the present system's strengths and weaknesses are needed to focus improvements. It is anticipated that proposed HACCP concepts will supplement the existing federal/state/industry cooperative program, not replace it. This video points out that HACCP could selectively focus on current critical public health deficiencies and provide both states and industry with economic incentives for full compliance with prescribed public health practices.

## **BACKGROUND TO VIDEO**

### **Sanitation Requirements and Regulatory Controls**

Specific sanitation practices designed to address the unique problems posed by eating raw molluscan shellfish were first developed in 1925. The shellfish industry and states sought the assistance of federal public health officials during an extensive typhoid fever outbreak. Widespread illnesses from consuming contaminated raw oysters had eroded consumer confidence such that the livelihood of the industry was in question. The need for public health controls was apparent. The tripartite partnership of the industry, federal

government and state public health officials, developed fundamental sanitary controls for producing molluscan shellfish that form the basis of the NSSP. This program is an ongoing cooperative effort to produce a HACCP umbrella of sanitary controls and guidance to improve the safety of molluscan shellfish from point of harvest to wholesale distribution. This video details the stringent requirements and responsibilities for classifying shellfish harvesting areas, harvesting, processing and distribution of shellfish.

As filter feeders, molluscan pump and strain vast quantities of seawater everyday. Through this natural feeding activity, they can concentrate bacteria, viruses, and other contaminants and marine toxins from surrounding waters. Therefore, shellfish safety begins at the harvesting site.

Harvesting areas must be tested and found to be safe before harvesting is allowed. Untested waters and those not meeting stringent analyses and monitoring criteria are deemed unsafe and harvesting is prohibited. Special management and processing techniques can be applied to harvesting areas which are intermittently contaminated, and to resources which are mildly contaminated.

Once areas are properly classified it is essential that harvesting be allowed only in prescribed areas. Harvesting in prohibited or closed areas, commonly called "bootlegging," negates all public health controls. Most illness outbreaks associated with raw shellfish are the result of improper classification of harvesting areas or illegal harvesting. However, sanitation and temperature controls during harvesting, processing and product distribution are needed to maintain both product quality and safety. Proper product tagging and record keeping must be capable of tracing a product back to the harvesting site should a problem arise.

### III. Purpose

A. Detail description-this project was developed to begin a comprehensive educational program about the the Hazardous Analysis Critical Control Point (HACCP) system of seafood inspection. To our collective knowledge (industry, academic and government) there are no videos currently available of this nature.

Overall, the project proceeded with very little impediment. Much of the work presented new concepts to present inspection systems; hence, there was considerable time spent on education and review. Different philosophies of the regulatory agencies of the U.S. Government, this was particularly true of what constitutes a critical control point. It was decided early on that a CCP would include both food safety and economic fraud issues.

#### B. Objective

The specific objectives of the project were to promote to the: industry (both domestic and international), government (both U.S. & foreign), academic and consumer, the benefits of using a HACCP based quality assurance/food protection system.

### IV. Approach

#### A. Detailed description of the work

1. Meeting with pertinent organization (Govt., industry and academic)
2. Research of existing technical literature, documentation etc.
3. Decisions on best, most appropriate approach, the actual scripting, review and critique

#### 4. Video shooting and production

Following are the accomplishments and finding as a result of this project/program

1. Documented in video form the advantages of HACCP inspection approach to minimizing food borne disease
2. Development of an educational video to be used across the entire spectrum of the seafood industry
3. Alerted retailers to the dangers of handling molluscan shellfish and recommended guidelines
4. Layed the groundwork for an educational program to be used
5. Development of support (educational) materials
6. Review of final product with government, trade and other interested parties. Six copies of the final versions of each video (retail & wholesale/distributor submitted)

#### V. Funding

##### A. Actual accomplishments and findings (See attached)

No problems developed which resulted in a less than satisfactory result in future FDA/National Marine Fisheries Service projects.

#### VI. Evaluation

This project is an intregal part of the overall plan of the U.S. FDA and the U.S. Dept. of Commerce new seafood inspection system. The presentation centers on understanding HACCP and uses Molluscan Shellfish as the example. The project divides the HACCP model into two distinct responsibilities: 1.) the distributor/supplier and 2.) the retailer, and sets down the proper procedure for developing a HACCP compliance system.

The goals have been accomplished since the video is currently being utilized by industry, academic and government, with extremely high acceptance. The philosophy and content of the educational material parallels the specific concepts and goals of both U.S. FDA, U.S. Dept. of Commerce, and National Marine Fisheries Service. This program is currently available to the industry and has been used to illustrate and assist in the development of HACCP models for the new FDA/NMFS Seafood initiative.

The value of this is the development of a better inspection system for the fishing industry-enabling a safe, high quality product to the market place. The general consensus of both industry and government is that the use of HACCP based inspection program will not only benefit the seafood industry with a high quality product but also at a lesser inspection cost. It is important to understand a program of this magnitude requires federal assistance the acceptance of a new inspection (HACCP) program and the educational program needed to show coordination and cooperation of both industry and government.

#### VII. Conclusion

Training is essential to implementation of the HACCP concept. It informs those who will be involved with the concept and stimulates them to develop and

apply HACCP system. By focusing training on HACCP concept, food handler and manager training can be streamlined so that only a few topics relating to product-specific hazards, critical control points, and monitoring procedures are emphasized rather than being courses on basic bacteriology, dish washing and vector control. Similarly, training for regulatory officials can be focused on critical operations that will prevent foodborne diseases and spoilage, rather than on aesthetics.

HACCP is the "state of the art and science" of food safety. Quality control and food safety programs must depart from ineffective and inefficient elements of traditional food protection activities. Leaders in these fields must stimulate universal acceptance of HACCP system and guide its implementation in all food operations.

### **What further work needs to be done**

There are deterrents to implementing HACCP systems. The primary deterrents are:

1. The inspection mentality and defensiveness to change is the major deterrent to implementation of HACCP systems.
2. Misunderstanding of the HACCP concept is another deterrent. Many persons have incomplete understanding of the HACCP concept. They often think of HACCP as an intensified inspection, a gigantic record-keeping task, or some special concern that they have been advocating.
3. Untrained co-workers and supervisors back on the job expect newly trained persons (who go back to their previous job to do the same thing as they did before the training).

Persons in both regulatory and quality control activities have traditionally put emphasis on inspection of food processing, and preparation environments and on the testing of finished products in their food protection programs. They resist changing their approach. Education about the HACCP concept and an ability to set priority for items in sanitary codes and food processing steps according to relative importance to food safety are needed to hurdle this barrier.

The second deterrent is ageless whenever a new idea is introduced. The HACCP concept, however, is an exactly defined system of interrelated components, each having specific definitions. Education and time seem to be the only remedies.

The third deterrent is a problem with most job-related training. Having a management commitment to the implementation and maintenance of the HACCP system and training supervisors first, will minimize difficulties created by this deterrent.

For HACCP to become the keystone of food safety and quality control, these deterrents must be overcome. This is our challenge.