Executive Summary

Survey questionnaires were distributed to approximately 5,000 seafood companies across the United States who had sent at least one employee to a three-day Seafood Alliance HACCP training course. An initial survey was conducted in New York, Connecticut and Rhode Island in 1998. A second survey was conducted in November 1999. A total of 744 responses from 43 states and 3 territories were returned. The survey's intent was to: document the time, effort, and resources that the seafood industry devoted to implementing HACCP; identify changes or problems that occurred in this process; and plan for additional training activities that might be needed. Of the firms that returned a survey, 59 percent were wholesalers/distributors and 35 percent were processors. Responses were received from firms of all sizes. Firms who returned survey questionnaires were characteristic of the U.S, seafood industry, and the largest portion were small firms. 53 percent had less than 10 employees, and 42 percent had average annual sales were less than $1 million. 62 percent had average annual sales less than $3 million.

Questions designed to evaluate the impact of the HACCP training effort indicated that 77 percent of the firms felt that they would **not** have been able to develop a HACCP plan and comply with the FDA regulation without the Alliance training course. Over 90 percent of the respondents felt that the Alliance training course provided the information that they needed to develop a HACCP plan, understand FDA's guidance information, and comply with the FDA seafood HACCP regulation. Interest was expressed in additional training courses that were 1 day in length or less on the following topics: current FDA guidance on hazards and controls, sanitation, importer requirements, and specific hazards for bivalve mollusks, and microbiological hazards in ready-to-eat products. Approximately two thirds of the survey respondents expressed an interest in participating in training courses that were delivered over the Internet.

Eighty-eight percent of the firms who returned a survey indicated that employees from the firm wrote their HACCP plan. The average number of hours reported for HACCP plan development was 68.7 hours with a range from 0.5 to 1,200 hours. The average hourly wage reported for those who developed the HACCP plan was $19.47 per hour with a range from $6 to $500 per hour. Average calculated cost for HACCP plan development was $1,338 plus $567 for training for a total cost of $1,905. Firms reported that the Hazard Analysis took an average of 16.7 hours, developing the HACCP plan 29.8 hours, developing HACCP records 13.7 hours, and developing sanitation procedures and records 13.3 hours. The relative cost burden for the smallest firms expressed as a percent of annual sales was 10 times higher than for the largest.

Survey respondents estimated that the average amount of money invested to meet the HACCP requirements of the FDA regulation was $15,077.00 with a range from $0 to $750,000. Smaller firms invested as much money as medium sized firms, and the investment made by the largest firms was significantly higher. The relative cost as a percentage of total annual sales was as much as 10 times greater for the smallest firms as compared to the largest.

The following equipment items were reported to be purchased, modified or upgraded most frequently to meet the HACCP requirements of the FDA regulation: thermometers, coolers, other monitoring devices, product test kits, ice machines, and computers. The specific changes most frequently identified in plant operations or facilities that were made to comply with the HACCP requirements of the FDA regulation were: using thermometers or other monitoring devices more frequently; changing how products are stored and how storage conditions are monitored; changing the way some or all products are evaluated at receiving; verifying one or more

processing procedures to control a food safety hazard; using more ice during storage, display, and shipping to control product temperature.

Survey respondents estimated that the average amount of money invested in equipment or services to meet the sanitation requirements of FDA regulation was $10,190 with a range from $0 to $500,000. The relative cost burden for the smallest firms was ten times higher than for the largest firms. The top five types of sanitation equipment, supplies, or services that were reported to be purchased, modified, or upgraded were: new sanitizer or cleaner; employee supplies; hand wash stations; hand sanitizer; and wall or ceiling surfaces. The specific changes made in plant facilities identified most frequently to meet the sanitation requirements of the FDA regulation were: changed cleaning and sanitizing procedures; conducting formal or informal employee sanitation training programs; purchasing, upgrading or modifying physical structures such as floors, walls, ceilings, drains etc.; purchasing or upgrading equipment such as sinks and hand wash stations; changing company policies regarding employee health and hygiene.

Survey respondents reported that the average amount of time spent on the routine requirements of the HACCP and sanitation components of the FDA regulation was 14.1 hours per week with a range from 0.5 hours to 300 hours. Average annual costs of these routine requirements were calculated to be from $10,920 to $14,174 per year. The activities reported to take up the majority of the time spent on the routine requirements of the FDA regulation in order were: product handling procedures, sanitation procedures, monitoring procedures; monitoring records; and sanitation records. Total annual cost was calculated to be $7,935 for the smallest firms and $52,141 for the largest. The relative cost burden for the smallest firms was 4 times higher for processors and 8 times higher for wholesalers as compared to the burden for the largest firms.

Firms were asked to identify the major benefits and disadvantages associated with the implementation of the HACCP system. The three most frequently identified benefits were: better understanding of the food safety hazards that could affect their products; better understanding of prevention and control of safety hazards that affect products; increased overall confidence in the safety of the seafood products sold. The three most frequently identified disadvantages were: cost of developing and implementing the HACCP plans; cost of maintaining the HACCP system; and impact on employees including increased wages, workload or compensation costs.

The total cost of implementing HACCP and Sanitation requirements and meeting the routine requirements for one year was calculated to be $17,495 for the smallest firms and $93,430 for the largest firms. The average cost burden expressed as a percentage of annual sales was seven times higher for the smallest firms as compared to the largest.

Seventy-eight percent of the survey respondents reported that the price of the products that they sell has not increased because of the requirements of the HACCP regulation, and 85 percent reported that they did not hire any new employees. Ninety percent indicated that they felt that the industry had benefited from HACCP training, and 86 percent agreed that the industry had benefited by implementing HACCP. However, only 66 percent felt that the overall benefits of implementing HACCP would outweigh the costs for their company, and 61 percent felt that consumers would benefit from the HACCP requirements. A variety of industry comments reveal that significant improvements have occurred in the industry's food safety and sanitation knowledge that has led to improvements in product safety, and quality. There is also a significant industry frustration over the paper work associated with the FDA seafood HACCP regulation.

Table of Contents

Acknowledgements

This study was conducted for and funding was provided by the **National Seafood HACCP Alliance for Training and Education**. The Seafood HACCP Alliance is a cooperative effort involving industry, government and university based Sea Grant programs across the country. The Seafood HACCP Alliance is currently supported with equal contributions from the National Sea Grant Program, the Association of Food and Drug Officials, and the U.S. Food and Drug Administration. The Alliance's mission is to provide uniform education through training courses designed for the diverse sectors of the seafood industry and the corresponding regulatory or inspection authorities. The principal organizations involved in the Seafood HACCP Alliance are University, Sea Grant or Cooperative Extension programs, the U.S. Food & Drug Administration, the National Marine Fisheries Service, the U.S. Department of Agriculture, the Association of Food and Drug Officials and their affiliate organizations, the Interstate Shellfish Sanitation Conference, the National Fisheries Institute and the National Food Processors Association.

The author also acknowledges the support and advice provided by the New York Seafood Council and its President Roger Tollefsen. The New York Seafood Council played an integral role in the success of the original project conducted in New York that made this national study possible. Roger Tollefsen also created and developed the database program that was used to tabulate the results of the national survey. His assistance was invaluable to the success of this project. The support, invaluable assistance and hard work provided by Karen Palmeri and Ellie Geosits was also key to the success of this project. Without their help we would not have been able to get this survey out and the results tabulated in such a short period of time. The assistance provided by Jane Christy and Denise Rooney of the Association of Food and Drug Officials who provided mailing labels for the survey recipients is gratefully acknowledged and appreciated. The assistance of the New York Sea Grant Institute and the Florida Sea Grant Program is also greatly appreciated. Appreciation is also extended to my colleagues John

Schrade of the Northeast Regional Office of FDA, Mike Halbert and Joe Corby of the NYS Department of Agriculture & Markets, Lori Pivarnik of the University of Rhode Island, Nancy Balcom of the Connecticut Sea Grant Program, Doris Hicks of the Delaware Sea Grant Program, Tom Rippen of the Maryland Sea Grant Program, Steve Otwell of the University of Florida, and Bob Kent of the New York Sea Grant Program for the advice and support that they've provided on this and other HACCP projects that I've been involved with over the years.

List of Tables and Figures

Introduction

The U.S. Food and Drug Administration published a final regulation on December 18, 1995 that requires all seafood processors in the U.S. and foreign countries that export seafood products to the U.S. to apply the food safety control system called HACCP (Hazard Analysis Critical Control Point) to their operations by December 17, 1997. A broad cross section of the seafood industry was required to comply with this regulation including traditional processors who manufacture, preserve, prepare, shuck, eviscerate, freeze or change seafood products into different market forms as well as wholesale, distribution or other firms that handle, store, hold, pack, or label seafood or engage in dockside unloading. Harvesters, retail establishments, and transportation companies were exempted from this regulation. Specific requirements were also included for seafood importers, smoked fish, and bivalve molluscan shellfish. Based on the cost analysis information contained in the Preamble of the final regulation (Federal Register, Vol. 60, No. 242, 12/18/95), FDA estimates indicate that approximately 5,000 domestic manufacturers and 1,000 importers in the U.S. would be affected by this regulation.

The FDA regulation is based on and incorporates the seven principles of the preventive food safety control system known as HACCP. Each firm is required to conduct a Hazard Analysis to identify any significant food safety hazards that are reasonably likely to occur for their unique operation. The Hazard Analysis process requires that firms consider the potential hazards associated with each species of fish or shellfish that they handle or process as well as the potential food safety hazards associated with each step of their operation. When significant food safety hazards are identified in this analysis, a HACCP plan is developed to prevent, eliminate or reduce the hazard to an acceptable level at critical steps in the operation. The HACCP plan identifies each significant hazard and the Critical Control Points (CCPs) in the operation where the hazard will be controlled. At each of these CCPs, critical limits are established along with monitoring and record keeping systems to demonstrate that the identified hazards have been controlled. Corrective actions are developed to ensure that procedures are in place to correct problems that may occur when established limits are not met and prevent unsafe products from entering the marketplace. Periodic procedures are also required to verify that the HACCP plan is working effectively. In addition to the HACCP controls, seafood firms are also required to monitor and keep records of their monitoring results and corrective actions for eight areas of sanitation identified in the FDA regulation.

The HACCP concept, the procedures and language needed to conduct a Hazard Analysis and develop a HACCP plan, and the specific guidance information developed by FDA to assist seafood businesses with this process were unfamiliar to most seafood businesses and many in the regulatory community. It was clear that training for the industry and regulators was needed for the transition to a HACCP based system. The FDA Seafood HACCP regulation also included a requirement that the development of the HACCP plan, record reviews, and periodic reassessment or modification of the HACCP plan must be conducted by a trained individual or by someone who is otherwise qualified through job experience. A national initiative called the Seafood HACCP Alliance was developed with funding support from the National Sea Grant College Program to develop and deliver a seafood HACCP training program. The Seafood HACCP Alliance was a collaborative effort of Sea Grant University Seafood Specialists, FDA, USDA, National Marine Fisheries Service, Interstate Shellfish Sanitation Conference, the Association of Food and Drug Officials, and industry trade organizations such as the National Fisheries Institute

and the National Food Processors Association. A standardized three-day training course was developed, and recognized by FDA as meeting the regulation's training requirement and as the curriculum by which other training programs could be evaluated. In the U.S., 475 individuals attended Train-the-Trainer courses that would qualify them to deliver this program. By February 2000, over 10,000 individuals had completed one of the 403 seafood HACCP training courses conducted in the U.S., and 770 individuals had completed one of the 30 courses conducted in other countries around the world. Seventy-six percent of the individuals who completed this training program were from the seafood industry. Federal and state food safety inspectors also needed to acquire training to understand HACCP, the FDA regulation and FDA food safety control guidance materials, and 17 percent of the people who completed this course were from federal, state or local regulatory agencies. Inspectors also attended a second two-day training course conducted by FDA that provided guidance on conducting HACCP inspections. Sea Grant and university seafood technology specialists played a lead role in organizing and conducting training courses around the country with assistance from FDA and state regulatory personnel, seafood industry groups and other professionals. These specialists also provided technical assistance to a wide variety of individuals businesses or business groups to help with the HACCP implementation process.

The HACCP Implementation Survey

Considerable time and effort was devoted to the HACCP training and implementation process over the past five years from the time that the final FDA Seafood HACCP regulation was published to the present. Seafood businesses needed to: obtain training to understand HACCP and the requirements of the FDA regulation; conduct a hazard analysis of the products they sell and their process; develop a written HACCP plan and appropriate monitoring records; implement the plan; develop sanitation procedures and monitoring records; and validate that their HACCP system was appropriate and working properly. Many seafood firms and regulatory officials expressed a desire to have someone document the time, effort, and resources that were devoted to the HACCP implementation process, and some of the changes that have occurred as a result of this effort. New York Sea Grant and the New York Seafood Council had developed and distributed a survey questionnaire in 1998 to collect this information. In 1999, the Seafood HACCP Alliance Steering Committee was provided with a copy of the New York survey report and decided to support a similar national survey. Ken Gall from New York Sea Grant and Cornell University conducted the national survey with funding from the Seafood HACCP Alliance project.

The purpose of the HACCP Implementation Survey Questionnaire was to:

- **Document the time, effort, and resources devoted by industry to implementing HACCP.**
- **Identify the changes and problems that have occurred during this process.**
- **Evaluate the impact of training programs.**
- **Help plan for any additional training activities that might be needed.**

Initially, the HACCP Implementation Survey Questionnaire was distributed to seafood businesses who had at least one employee attend and complete one of the 18 three-day Seafood HACCP Alliance training courses that were conducted in New York from November 1996 through May 1998. The questionnaire and a postage paid return envelope were mailed to 340

seafood companies in July of 1998. A follow up mailing was sent to the same companies again in August 1998. During this same period, it was decided that we would seek additional information from the surrounding states if possible. Ken Gall contacted Sea Grant colleagues Lori Pivarnik in Rhode Island, Nancy Balcom in Connecticut, and Tom Rippen in Maryland who distributed survey questionnaires in August and September of 1998. A total of 144 completed HACCP Implementation Survey Questionnaires were returned to the NY Sea Grant Extension Program office by October 15th, 1998. A Seafood HACCP Implementation Survey Report was produced by NY Sea Grant Seafood Specialist Ken Gall in April 1999.

The national Seafood HACCP Alliance Survey project was initiated in the fall of 1999. An edited version of the NY survey questionnaire was developed at that time. All of the original questions from the NY survey were used and simple editing changes included deleting several questions and adding two additional questions related to Internet training and computer availability. Survey questionnaires were distributed in November 1999 to 6,515 individuals from 4,707 seafood firms in all of the U.S. states except for New York, Connecticut and Rhode Island. U.S. firms who received the survey questionnaire included all of the individuals in the Association of Food and Drug Officials database of students who had completed a three-day seafood HACCP Alliance training course in the U.S. as of October 1, 1999. By April 1, 2000, 600 completed survey questionnaires were returned. Survey responses were entered into a database and combined with the 144 survey responses from the earlier NY survey. The results presented in this report are based on the 744 survey questionnaires that were returned in both the 1998 NY Survey and the 1999 Seafood HACCP Alliance national survey.

The overall response rate of the two combined surveys was approximately 14 percent. The data presented in this report represents the collective responses received from 14 percent of the seafood firms in the United States that had completed the three-day Seafood HACCP Alliance training course by October 1, 1999.

Profile of Seafood Businesses who Returned Survey Questionnaires

Several questions were included in the survey to develop a profile of the types of seafood businesses that returned a questionnaire. Respondents were asked to identify the state in which their business was located and the type of business activities that they conduct from a list of business types that were likely to have to comply with the FDA seafood HACCP regulation. Two questions were included to obtain measures of the size of the companies who responded to the survey. Respondents were asked to report the number of employees from a list than ranged from 1 to 5 to greater than 100 as well as their average annual sales using a range of choices from $500,000 or less to greater than $20 million.

Business Location of Survey Respondents

Survey questionnaires were returned from seafood businesses in 43 states and Puerto Rico, Guam and the Marianna Islands. 734 firms identified the state in which their business is located, and 10 firms chose not to provide that information. The majority of the survey questionnaires were received from the large seafood producing states and states with a large wholesale distribution industry. 70 percent of the survey questionnaires were from the following thirteen states: New York, California, Louisiana, Maine, Florida, Alaska, Maryland, Texas,

Massachusetts, North Carolina, Washington, New Jersey, and Connecticut. These states are reasonably representative of the variety and diverse types of businesses that make up the U.S. seafood industry. Survey responses from each of these 13 states will be included in this report in an attempt to characterize regional differences in survey results. The number of responses received from each of the other 30 states or territories was less than 20 each and in many cases only one to three responses were received from many states. Individual state responses from those states are not provided in this report. However, results from all of the states and territories are included in the overall compilation of results. Firms from all regions of the country returned the survey questionnaire, and the survey results indicate that the responses received can be characterized as reasonably representative of the seafood industry in the United States.

Table 1. Business location of the 744 seafood companies who returned the HACCP Implementation Survey Questionnaire.

Business Location	Number of firms who returned surveys
New York	85
California	64
Louisiana	58
Maine	55
Florida	47
Alaska	43
Maryland	29
Texas	28
Massachusetts	26
North Carolina	25
New Jersey	21
Washington	21
Connecticut	20
Pennsylvania	17
Virginia	17
Wisconsin	16
Illinois	16
Hawaii	15
Alabama	14
Georgia	14
Michigan	13
Rhode Island	13
Mississippi	12
South Carolina	10
New Hampshire	7
Minnesota	6
Missouri	5
Ohio	4
Colorado	3
Delaware	3
Iowa	3
Puerto Rico	3
Arkansas	2
Nebraska	2
Oregon	2

West Virginia	**2**
Guam	**2**
Marianna Islands	**2**
Indiana	**2**
Kansas	**1**
Kentucky	**1**
Montana	**1**
North Dakota	**1**
New Mexico	**1**
Nevada	**1**
Tennessee	**1**

10 Firms did not report their business location

Business Type of Survey Respondents

An attempt was made to characterize the type of business activity conducted by the firms that completed the survey questionnaire and their size. Survey respondents were asked to select from a number of choices that described their primary type of business activity, the number of employees, and their average annual sales. **Table 2** summarizes the type of business activity conducted by firms who returned a survey questionnaire. The majority, 415 or 59 percent, of firms who responded to this survey characterized their business as being a wholesaler or distributor. About one third, 252 or 35 percent of the respondents identified themselves as processors.

Table 2. Business type of all firms who completed the HACCP Implementation Survey

Type of Business*	Percent of all Firms who selected each business type
Wholesaler/Distributor	59%
Processor	35%
Harvester	10%
Retail Warehouse	9%
Importer	7%
Custom Packer	7%
Packing Dock	4%
Public Warehouse	2%
Other	8%
No Business Reported	5%

*Some firms selected more than one type of business.

These results are typical of what would be expected when the scope of coverage of the FDA seafood HACCP regulation and the make-up of the seafood industry in the U.S. is considered. The largest sector of the seafood industry in terms of number of businesses that were required to comply with the FDA regulation is the wholesale/distribution sector followed by the processing sector. The National Marine Fisheries Service publication Fisheries of the U.S. for 1998 indicates that there were 3,520 wholesale plants in the U.S. and 1,297 processors. Based on these figures the wholesale sector represents approximately 73 percent of the seafood plants in the U.S. and the processing sector 27 percent. If we compare these statistics to the type and number of

businesses who returned survey questionnaires, the survey responses received can be characterized as typical and representative of the sectors of seafood industry in the U.S. that were required to comply with the FDA Seafood HACCP regulation.

Other types of businesses that may have had to comply with all or part of the FDA HACCP regulation that attended Alliance HACCP training courses and returned a survey questionnaire included: 73 questionnaires from harvesters; 62 questionnaires from retail warehouses, 47 questionnaires from custom packers, 46 questionnaires from importers, 30 from packing docks, and 13 from public warehouses. Many firms checked more than one type of business activity from the menu of choices that reflected the variety of activities that they conduct. For this reason, the responses indicate: (1) The frequency with which firms who responded to the survey are engaged in that type of activity and (2). The sum of the reported percentages is greater than 100.

The type of firms who returned a survey questionnaire is further characterized by state in **Table 3**. This information is being provided to assist with the interpretation of specific survey questionnaire responses. The results reported in **Table 3** indicate that for most areas of the country, the majority of firms that returned a survey questionnaire were wholesalers or distributors. Sixty percent or more of the survey respondents from New York, California, Louisiana, Florida, Massachusetts, and North Carolina were wholesalers or distributors. For the other states, the number of wholesalers who returned survey questionnaires was larger than for any other industry sector except for the states of Maine and Alaska for which more processors returned survey questionnaires. For three states, Maryland, Texas and Washington, an approximately equal number of processors and wholesalers returned questionnaires.

Table 3. Percent of firms in each State who reported the four most frequently identified business types in the HACCP Implementation Survey questionnaire.*

State	Wholesalers	Processors	Harvesters	Retail Warehouses
Alaska	**28%**	**65%**	**23%**	**12%**
California	**61%**	**27%**	**9%**	**5%**
Connecticut	**50%**	**0%**	**45%**	**10%**
Florida	**86%**	**33%**	**9%**	**9%**
Louisiana	**63%**	**46%**	**7%**	**6%**
Maine	**55%**	**57%**	**4%**	**2%**
Massachusetts	**69%**	**31%**	**15%**	**4%**
Maryland	**48%**	**48%**	**10%**	**7%**
New Jersey	**47%**	**37%**	**0%**	**11%**
New York	**73%**	**13%**	**8%**	**8%**
North Carolina	**79%**	**17%**	**13%**	**25%**
Texas	**44%**	**40%**	**0%**	**4%**
Washington	**42%**	**42%**	**21%**	**11%**

***** Many firms reported multiple business types.

Because many firms conduct multiple activities, industry sectors such as harvesters and importers that are not be specifically required to have a HACCP plan were also represented. In

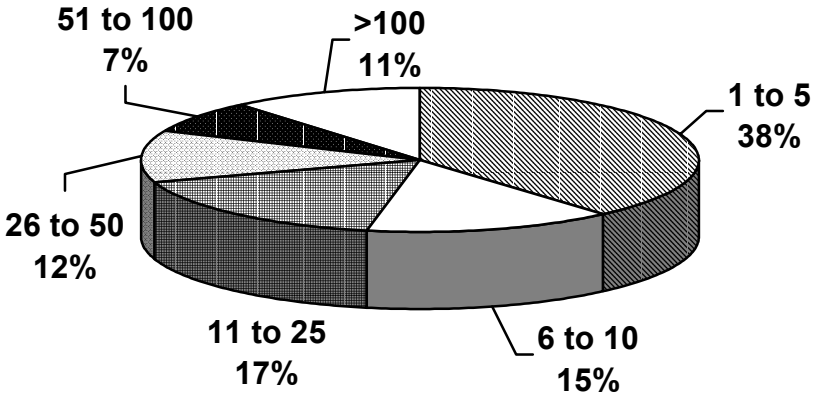
most cases these firms indicated that they were both a wholesaler or processor as well as a harvester or importer. Retail warehouses from all of the states returned survey questionnaires, and a significant number of questionnaires were received from firms involved in the importation of seafood products in California and New Jersey. A large number of firms engaged in harvesting activities in Alaska, Washington, and Connecticut also returned questionnaires. Most of the firms that reported harvesting activity are also likely to be engaged in some type of processing and/or wholesale activity. For example, in the state of Connecticut all shellfish harvesters are also considered shippers. Since most shippers in this area are likely to sell product in interstate commerce at times, it is likely that they would have had to comply with the FDA seafood HACCP regulation.

Business Size (Employees and Sales) of Survey Respondents

To more fully characterize the type of firms that completed this survey questionnaire, respondents were asked to indicate the number of employees and the firms' average annual sales. Six choices ranging from 1 to 5 to greater than 100 employees were provided, and seven choices ranging from $500,000 or less to greater than $20 million were given for total annual sales. *(See the survey questionnaire in the Appendix for the exact questions and choices that were given.)*

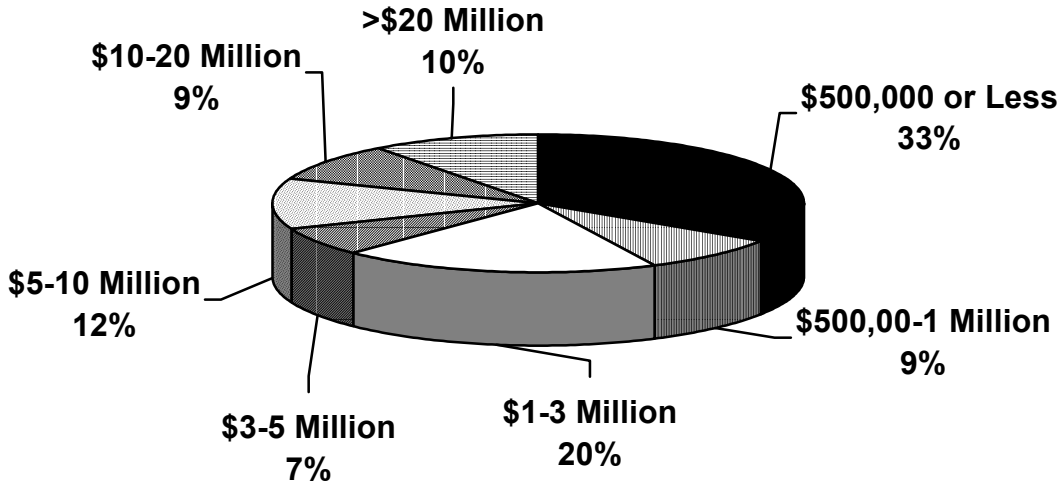
Over half of all of the 744 firms **(Figures 1 and 2)** that responded to this survey could be characterized as small businesses. Fifty-three percent of these firms reported that they had fewer than 10 employees, and 38 percent had fewer than 5 employees. Thirty percent of the survey respondents employed more than 25 individuals, and 18 percent of these employed more than 50 individuals.

Figure 1. Number of Employees reported by the 714 respondents who answered this question.



Forty-two percent also reported that their average annual sales were less than $1 million, and 33 percent had average annual sales less than $500,000. The majority of firms, 62 percent reported average annual sales less than $3 million. Larger firms also returned survey questionnaires, and 19 percent had annual sales greater than $10 million and over half of these had annual sales greater than $20 million. Eighty-nine of the survey respondents chose not to provide any information about their average annual sales.

Figure 2. Average Annual Sales reported by the 655 respondents who answered this question.



This data indicates that the survey respondents were typical and representative of the seafood industry in the U.S. Unlike many other food industries, the seafood industry still has a large number of small businesses that engage in a wide variety of activities. There are also a significant number of medium sized and large corporations in the industry, although in terms of numbers of firms the small companies predominate.

Table 4 compares the survey respondents' reported average annual sales to the type of business activity that was reported. This data indicates that both wholesale firms and processing firms of all sizes responded to the survey questionnaire. It also shows that over 50 percent of the survey respondents who identified themselves as wholesalers or processors were small firms with average annual sales of $3 million or less. Most of the firms engaged in harvesting activities were very small firms, and 70 percent reported having $500,000 or less in annual sales. Retail warehouses of all sizes responded to the survey questionnaire. Most of the retail warehouses were small firms with 58 percent having annual sales less than $3 million, but 26 percent were large firms with annual sales greater than $10 million.

Table 4. Reported average annual sales of HACCP implementation survey questionnaire respondents compared to business type.

Reported Average Annual Sales	Wholesaler	Processor	Harvester	Retail Warehouse
$500,000 or less	22%	32%	70%	35%
$500,000 to 1 Million	9%	6%	1%	8%
$1 to 3 Million	21%	17%	11%	15%
$3 to 5 Million	7%	8%	1%	3%
$5 to 10 Million	12%	13%	4%	2%
$10 to 20 Million	9%	9%	1%	7%
More than $20 Million	10%	7%	0%	19%
Sales Not Reported	10%	8%	12%	11%

There were some significant regional differences in the size of firms that responded to the survey questionnaire. Small firms with sales less than $3 million represented over 50 percent of the survey respondents from all states except California, Massachusetts, New Jersey and Texas. At least three-fourths or more of the firms who responded to the survey from Alaska, Connecticut, Maine, Maryland and Washington had annual sales less than $3 million, and most of those firms were very small with annual sales less than $1 million. Many states had a small number of large firms with average annual sales greater than $10 million. However, only 3 states, California, New Jersey, and New York, had a significant number of survey respondents from firms with average annual sales greater than $10 million. Forty-five percent of the survey respondents from New Jersey, 40 percent from California, and 28 percent from New York reported annual sales greater than $10 million. Both the type of firms that responded to the survey from each state and their size need to be considered when analyzing state responses to survey questions related to various components of the HACCP implementation process.

Table 5. Percent of firms in each State who reported each range of average annual sales in the HACCP Implementation Survey questionnaire.

State	< $1 Million	$1-3 Million	$3-5 Million	$5-10 Million	$10-20 Million	> $20 Million
Alaska	69%	8%	5%	5%	10%	3%
California	17%	15%	7%	21%	19%	21%
Connecticut	68%	11%	0%	21%	0%	0%
Florida	46%	14%	8%	13%	11%	8%
Louisiana	56%	24%	6%	6%	2%	6%
Maine	59%	15%	8%	10%	4%	4%
Massachusetts	25%	25%	5%	29%	8%	8%
Maryland	59%	19%	4%	15%	0%	3%
New Jersey	22%	28%	6%	0%	17%	28%
New York	30%	25%	6%	11%	13%	15%
North Carolina	42%	36%	11%	0%	0%	11%
Texas	41%	4%	15%	22%	11%	7%
Washington	61%	11%	0%	11%	11%	6%

Survey Results

HACCP Training

The first seven questions in the HACCP Implementation Survey Questionnaire related to the three-day Seafood HACCP Alliance Training course that individuals from seafood firms across the country had attended up to October 1, 1999. The questions were designed to obtain feedback on whether the training program was successful in providing the information that was needed for seafood businesses to understand the HACCP concept and develop a HACCP plan consistent with the FDA regulation and FDA guidance materials.

To evaluate the overall impact of the training effort, survey respondents were asked "Do you think that your company would have been able to develop a HACCP plan to meet the requirements of the FDA regulation if you had not attended the training course?" The importance and need for training was clearly demonstrated in the response to this question.

77 percent of the 734 respondents who answered this question indicated that they would not have been able to develop a HACCP plan to comply with the FDA regulation without the training course.

Even though seafood industry leaders and the regulatory community had been discussing HACCP for years, it was clear that many seafood businesses did not understand the HACCP concept and its practical application to the handling and processing of seafood products. For those involved in the national Seafood HACCP Alliance training program, it also seems clear that the program met an important need and played a key role in helping the industry and regulatory community make the transition to HACCP.

In order to comply with the FDA regulation, seafood firms had to have an understanding of: (1) Basic HACCP principles, (2) The FDA regulation, and (3) The FDA Fish and Fisheries Products Hazards and Controls Guide which provided guidance information that was essential for most firms to complete their Hazard Analysis and develop a HACCP plan. The next two survey questions were designed to identify whether or not the training program was successful in conveying the information that the seafood industry needed to understand basic HACCP principles and the FDA seafood HACCP regulation.

Ninety-nine percent (99%) of the 740 survey respondents who answered Question 2 reported that the training course provided them with a basic understanding of HACCP principles.

Clearly the training program was very successful in introducing the HACCP concept to industry participants.

Another goal of the training course was to help the seafood industry understand the FDA's Seafood HACCP regulation.

Ninety-two percent (92%) of the 722 survey respondents who answered Question 3 indicated that "by the end of the course they understood what they needed to do to comply with the FDA seafood HACCP regulation."

The fact that fewer individuals understood the FDA regulation probably relates to the fact that many in the industry were unfamiliar with the language used in regulations. For many individuals who attended the training, this was their first exposure to this type of regulation and the regulatory language used by federal agencies.

To obtain an understanding of what specific topics in the training course were most useful or important to participants, survey respondents were asked to identify the most important things that were learned in the HACCP course." Five choices were provided along with an opportunity for respondents to add their own topic or comments. The responses received from the 734 survey respondents who answered this question are summarized below.

"What was the most important thing that you learned in the HACCP course"

418 - How to develop an appropriate HACCP plan for your operation.
297 - The requirements of the FDA Seafood HACCP regulation.
229 - How to prevent or control the food safety hazards associated with your products
223 - What food safety hazards could be associated with your products.
157 - Basic sanitation requirements and Good Manufacturing Practices.

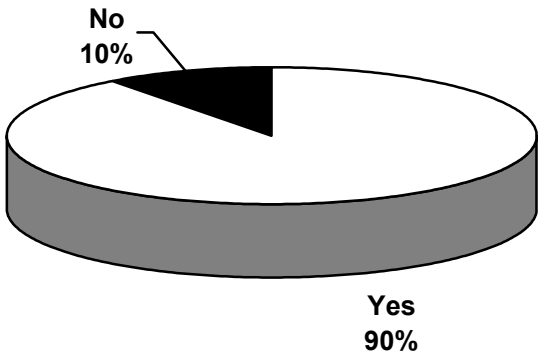
37 – Other: Everything taught in the course was important. All of the above and team work. Improving management of daily processes. How industry can work together to a common goal. How to develop a HACCP plan should've been most important. All of the above. HACCP was not as ominous as first imagined. That a HACCP plan was not needed (canned salmon labeling warehouse). Frozen seafood is practically safe for overseas trade. The paperwork is absolutely ridiculous. This should be required of all fresh food items. How to keep records of SSOPs. Why there are required procedures. It costs more money and time than expected. That HACCP is misdirected and overly burdensome. How to handle my product. How to keep records that demonstrate compliance. The need to document a written plan. We are doing everything just not recording it. How to do useless paper work. Local inspectors could more effectively distribute information. The records were somewhat complicated. The fox guards the chickens. That our first attempts were sorely inadequate. Why start in the middle and not cover boats and retail? That we needed to set aside more time in our already busy schedule to satisfy the government. That I needed a plan for frozen products. They are all equally important that is why they are part of the plan.

10 – Did not answer this question.

From these responses it is clear that most individuals were motivated to attend the HACCP course to learn how to develop a HACCP plan for their operation and to learn what they needed to do to comply with the FDA regulation. This course provided an important opportunity to teach or re-enforce a number of important food safety concepts. Although many individuals were generally aware of common seafood safety hazards, the training course and FDA guidance materials significantly enhanced general industry knowledge about both food safety hazards and effective control strategies. All of the comments provided by respondents are included in the "Other" response category. These comments demonstrate that some firms saw positive impacts from training while others were frustrated with record keeping and regulatory aspects of the seafood HACCP regulation.

The first four survey questions attempted to document the impact of the Seafood HACCP Alliance training course and evaluate whether or not the important components of the training program were successfully conveyed. Question 5 attempted to evaluate the industry's perception about whether or not the HACCP training effort was beneficial to the seafood industry. **Figure 3** shows that the vast majority (90 percent) of the firms who participated in HACCP training felt that the industry has benefited from the training experience, and the knowledge and skills provided in this training program were beneficial to the industry as a whole.

Figure 3. Do you think that the seafood industry has benefited from HACCP training?



Another survey question related to training was designed to help assess and plan for additional training needs (if any) identified by the seafood industry. To determine if the industry was interested in additional training, respondents were asked, "Do you think that we should conduct additional training courses on specific food safety or HACCP related topics for the seafood industry?"

Sixty-two percent (62%) of the 698 survey respondents who answered this question indicated that additional training courses should be conducted.

Almost two-thirds of the respondents felt that some additional training courses would be useful. Many firms that answered in the negative may have felt that they now had access to all of the information that they needed after attending the HACCP course, and that additional training was not needed or desired.

Those survey respondents who indicated that additional training courses should be conducted were asked to identify what specific topics should be addressed by future training programs. Survey respondents were given ten choices for possible training programs and an opportunity to identify other programs or topics not listed. The responses received are summarized in **Table 6**. This question was answered by 497 of the survey respondents. Many of those who did respond selected more than one topic.

Table 6. What courses would you or your employees attend or what courses would you encourage your customers (firms not covered by the FDA regulation) to attend?

308 - Yearly update session covering changes in FDA guidance on hazards and controls.
171 – Short (1 day or less) training sessions on specific seafood safety hazards.
Topics that would be of most interest:
146 – Handling and regulations for bivalve molluscs (e.g. clams and oysters).
136 – Controlling microbiological hazards in cooked or ready-to-eat products.
120 – Preventing scombroid poisoning (histamine).
103 – Process controls for smoked and/or vacuum packed fish.
79 – Procedures for controlling hazards on fishing vessels.
153 – Developing a Sanitation Standard Operating Procedure with records.
147 – Basic employee sanitation training.
139 – Importation requirements of the FDA Seafood HACCP regulation.

29 – Other topics: End user safety – cross contamination in restaurants. Refresher courses for new employees. Controlling hazards for aquaculture products. General review of HACCP. How to properly identify all fish. Get government to work individually with us to develop a plan they will accept rather than requiring a 3-day meeting. All of the above has been addressed time and again. Distribution and shipping. Controllable transportation and repackaging of products. Regulation of transport between custodians. Controlling hazards at restaurants, warehouses, and supermarkets. HACCP regulations pertaining to warehousing only. Basic biology/science. Stone crab claws. Standards for FDA requirements on seafood. All of the above. Restaurants should be included in all training courses. Computer related automation of paperwork. What is the best way of processing local catch and how to handle spoilage? Penalty for violating HACCP standards.

247 – Did not respond to this question.

Most of those who expressed an interest in additional training indicated that they would attend a yearly update session. Most likely this interest relates to the yearly validation requirement of the HACCP plan to ensure that it is effective and appropriate for the operation. In 1999 the Seafood HACCP Alliance in collaboration with FDA developed a one-day "Encore" training course designed to assist companies that were experiencing difficulties in developing or implementing their HACCP plans. The Encore course also provided updated guidance on specific food safety hazards that will be incorporated into the next edition of the FDA's "Fish and Fishery Products Hazards and Controls Guide". Additional update courses for the seafood industry may need to be scheduled periodically to meet this need. The other primary area of interest was in short focused training sessions on specific hazards related to higher risk products such as bivalve molluscs, ready-to-eat products, and scombroid fish. There was also an interest in additional information on sanitation. The results of this survey confirm that many in the industry perceive the same training needs as the Seafood HACCP Alliance and regulatory community. Deficiencies in sanitation were one of the most frequently identified problems in inspections conducted in 1998. The Seafood HACCP Alliance has developed a one-day course specifically designed to provide training on monitoring and controlling the eight areas of sanitation identified in the FDA regulation. This course was introduced to prospective trainers in Train-the-Trainer programs conducted by the Seafood HACCP Alliance in February and March 2000. Specific courses focusing on higher risk products are also being discussed. FDA district offices have also organized and conducted specialized "intervention courses" for specific segments of the seafood industry to help them understand and comply with regulations related to some products such as smoked fish and certain industry sectors such as importers. Additional courses are likely to be developed over time to meet these and other emerging industry needs.

A final series of questions was included in the survey questionnaire to help educators and trainers look to the future in terms of alternative training delivery mechanisms. Although almost 11,000 individuals had completed the Seafood HACCP Alliance training course by February 1, 2000, there is an ongoing need for training for both the seafood industry and the regulatory community. There are also significantly fewer individuals who are currently actively involved in delivering the basic Alliance HACCP training course. In anticipation of the need for alternative training mechanisms, the Seafood HACCP Alliance formed an Alternative Training Committee in 1998. This committee has examined alternative delivery mechanisms and determined that an Internet based delivery system would be most effective in meeting the training needs of the next decade. The Alliance's Alternative Training Committee is currently engaged in a project funded

by the Cooperative State Research, Education and Extension Service of USDA to convert the basic HACCP training course to an Internet delivered distance education format. This course is expected to become available in 2000. To assist with this project two survey questions were included to determine if the seafood industry would be likely to use training courses delivered over the Internet and what computer equipment they had access to at their business location and at home.

Figure 4. "Would you use training courses for yourself or your employees if they became available over the Internet?"

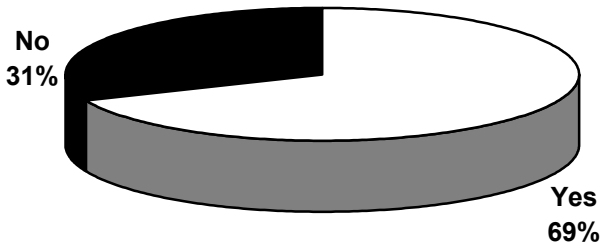


Figure 4 shows the responses received from 573 individuals who responded to the survey question that asked if they would use training courses if they were available over the Internet. Clearly there is considerable seafood industry interest in accessing training materials via the Internet. Slightly more than 2/3 of the survey respondents indicated that they would use the Internet for training. This is a significant portion of the seafood industry, and as the Internet continues to expand and be more widely used this number is likely to increase. An Internet-based delivery mechanism could be particularly advantageous to small businesses with one to three employees because they may literally have to shut down their operation to participate in training programs. Larger companies could also use this mechanism to train additional employees to help them better manage their HACCP program.

Table 7. Industry respondents' access to computer technology at their business and at home.

	At my business	At home
I don't have access to a computer	**113**	**93**
I have access to a computer	**262**	**243**
I have access to a computer connected to the Internet	**197**	**229**
I have access to a computer with a CD-ROM drive	**221**	**222**
I have access to a computer with CD-ROM & Internet connection	**275**	**291**
I have access to a computer with a DVD/CD-ROM drive	**27**	**46**
I have access to a computer with DVD/CD-ROM & Internet	**45**	**73**

To assess the seafood industry's current capabilities related to computer technology, survey respondents were asked to identify what type of computer system they have access to at their business and at home. The responses received from the 577 seafood firms who responded to the final question in the survey questionnaire regarding access to computer technology are shown in **Table 7**. A significant portion of seafood firms have access to computer equipment both at home

and at their place of business that can be used to access training programs delivered via the Internet or via CD-ROM. Both Internet and CD-ROM delivered educational programs could be effectively used to provide training to a wide range of seafood businesses across the country.

HACCP Plan Development and Costs

A series of survey questions were included to determine how seafood firms conducted the process of developing a HACCP plan for their operations and the amount of time and resources that were devoted to this effort. Survey Question 8 was included to determine whether or not survey respondents developed and wrote their own HACCP plan or utilized outside consultants or other experts. 733 of the survey respondents answered this question.

88 percent of the survey respondents reported that one or more of their company's employees wrote their firm's HACCP plan.

This confirms that most seafood businesses in the U.S. elected to develop and write their own HACCP plans rather than rely on consultants or outside expertise to develop it for them. These results are not unexpected when the profile of the companies who returned a survey is considered. A significant portion were small companies who most likely did not have the resources or did not have the type of operation that was complex enough to require the services of a consultant. This is also an indication of the impact of the national Seafood HACCP Alliance training effort which provided the tools and information needed for firms to develop and write their own HACCP plans.

Time Spent on HACCP Plan Development

Those firms who did develop their own HACCP plan were asked to **"estimate how much time your company spent developing and writing your HACCP plan." Table 8** provides the overall data for the 610 survey questionnaires that answered this question.

Table 8. Number of hours spent developing and writing the HACCP plan.

Mean	**68.7 Hours**
Range	**0.5 to 1,200 Hours**
Median	**30**
Standard Deviation	**121.2**
Number of Responses	**610**

The results reported in **Table 8** indicate that on average, firms spent approximately 69 hours or 8.6 working days (8 hours/day) writing their HACCP plan. There was a significant range from one half hour to 1,200 hours (150 working days). The amount of time reported to have been spent on HACCP plan development is likely to be directly related to: the complexity of the firm's operations; the scope of activities that were included in the estimate for HACCP plan development; and the skills and level of understanding of HACCP systems and FDA guidance

materials (Hazards and Controls Guide) that had been acquired by the individuals involved in writing the plan.

Table 9. Number of hours spent developing and writing the HACCP Plan compared to average annual sales.

Average Annual Sales	Mean	Median	Range	Standard Deviation	Number of Responses
$500,000 or less	**27.7**	**12**	**1-400**	**48.8**	**178**
$500,000 to $1 Million	**58.6**	**24**	**1-1,200**	**170.0**	**51**
$1 to $3 Million	**63.6**	**30**	**1-500**	**82.8**	**112**
$3 to $5 Million	**74.9**	**50**	**4-200**	**62.2**	**35**
$5 to $10 Million	**95.3**	**48**	**1-832**	**137.4**	**66**
$10 to $20 Million	**164.7**	**74**	**3-1,000**	**220.2**	**49**
Greater than $20 Million	**106.4**	**50**	**3-800**	**151.8**	**60**

Table 9 tabulates the responses related to the time spent on HACCP plan development by company size. Using average annual sales as an indicator of company size, the amount of time spent developing the plan increased as the size of the company increased. The smallest firms on average spent the least amount of time and the larger firms spent the most. This is to be expected if the assumption is made that as a firm's size increases they are likely to handle more products and/or engage in more complex processing activities. The only significant deviation from this trend was the decrease in hours spent developing the HACCP plan of the firms with sales greater than $20 million as compared to firms with sales from $10 to $20 million. This could be explained by efficiency if the assumption is made that the largest firms may have had employees with more training and focused technical skills who also had more of an applied knowledge of HACCP principles.

Table 10. Number of hours spent writing and developing the HACCP Plan reported by wholesalers compared to average annual sales.

Average Annual Sales	Mean	Median	Range	Standard Deviation	Number of Responses
$500,000 or less	**27.1**	**16**	**1-360**	**46.8**	**79**
$500,000 to $1 Million	**64.5**	**24**	**1-1,200**	**203.1**	**34**
$1 to $3 Million	**66.1**	**30**	**1-500**	**86.7**	**77**
$3 to $5 Million	**69.0**	**40**	**4-200**	**65.1**	**25**
$5 to $10 Million	**93.0**	**40**	**3-832**	**156.0**	**38**
$10 to $20 Million	**152.8**	**50**	**3-1,000**	**212.6**	**30**
Greater than $20 Million	**78.5**	**40**	**3-480**	**100.6**	**38**

Tables 10 and 11 show the number of hours spent on developing and writing the HACCP plan reported by the two most frequently identified business types, processors and wholesalers and company size as indicated by average annual sales. As with the overall data reported in **Table 9** the amount of time reported for HACCP plan development increased for both wholesalers and processors as company size increased. The amount of time reported for the smallest wholesalers and processors did not appear to be significantly different. However, for the larger firms, this data indicates that processors spent more time developing their HACCP plans than wholesalers

did. There was also a decrease in the amount of time reported by both the largest wholesalers and the largest processors (greater than 20 million in annual sales) as compared to firms in the next smaller category ($10-20 million in annual sales). This tends to give additional credence to the hypothesis that the largest firms were more efficient because of their access to employees with more HACCP training and/or technical skills.

Table 11. Number of hours spent developing and writing the HACCP Plan reported by processors compared to average annual sales.

Average Annual Sales	Mean	Median	Range	Standard Deviation	Number of Responses
$500,000 or less	30.6	16	1-360	54.8	63
$500,000 to $1 Million	153.7	40	3-1,200	339.4	12
$1 to $3 Million	68.4	40	1-500	89.3	36
$3 to $5 Million	92.9	80	12-200	64.6	16
$5 to $10 Million	145.9	60	20-832	183.6	25
$10 to $20 Million	185.2	80	20-1,000	238.0	19
Greater than $20 Million	180.1	100	5-800	229.8	17

Table 12 compares the time spent developing and writing the HACCP plan by firms from the 13 states that provided 70 percent of the survey responses to characterize regional differences in survey results. This data shows that there was a fairly wide range in the number of hours spent developing the HACCP plan.

Table 12. Number of hours reported to have been spent developing and writing the HACCP Plan by state.

State	Mean	Median	Range	Standard Deviation	Number of Responses
Texas	107.9	40	3-500	150.6	26
California	96.3	60	4-500	113.1	49
Washington	91.9	30	2-400	126.2	17
Alaska	82.4	50	1-360	94.0	33
New Jersey	82.1	32	8-600	146.8	16
Louisiana	64.0	20	1-1,200	174.0	48
New York	60.8	25	2-1,000	128.1	74
Florida	52.1	34	3-250	61.0	38
Massachusetts	48.1	40	6-200	51.2	21
North Carolina	41.8	24	1-200	50.8	21
Connecticut	31.6	12	1-120	38.5	19
Maine	31.3	20	1-120	32.1	46
Maryland	27.0	20	2-115	28.5	23

Firms in Maryland reported spending the least amount of time which on average was one-fourth of the time that firms in Texas reported for HACCP plan writing and development. There does not appear to be a discernable relationship between the amount of time spent on HACCP plan development and region of the country. The mean reported for firms in Louisiana, New York and

Alaska were closest to the overall national average. One explanation for the observed trends in this data is likely to be related to the size of firms that returned a survey from each state as summarized in **Table 5**. California, New Jersey, Massachusetts, Texas, and New York had the highest number of survey respondents from large firms with average annual sales greater than $5 million. Respondents from California, Texas and New Jersey also reported an average time spent developing the HACCP plan that was higher than the overall national average. Of the states that had the largest proportion of small companies, Alaska, Connecticut, Maine, Maryland, and Washington, the three Eastern states reported the lowest amount of time spent on development of their HACCP plans. However, even though both Alaska and Washington had a high proportion of small firms, the reported average time spent on HACCP plan development was higher than the overall national average. It is unclear why the smaller firms in this region of the country spent more time on HACCP plan development. Based on the comparative data for these 13 states, it appears likely that the differences observed in the average time spent developing and writing the HACCP plan is largely related to nature of the seafood industry as characterized by the size and complexity of the companies who returned surveys from that state.

The survey questionnaire also asked firms to report the amount of time that was devoted to each of the components of the FDA Seafood HACCP regulation including: conducting the Hazard Analysis, developing the HACCP Plan, developing HACCP records, and developing Sanitation procedures and records. The results of the survey responses are summarized in **Table 13**.

Table 13. Time devoted to each component of the FDA Seafood HACCP regulation.

	Mean	Median	Mode	Range	Standard Deviation	Number of Responses
Conducting a Hazard Analysis	**16.7 Hours**	**5 Hours**	**1 Hours**	**0.1 to 300 Hours**	**34.2**	**557**
Developing the HACCP Plan	**29.8 Hours**	**10 Hours**	**2 Hours**	**0.1 to 900 Hours**	**66.1**	**559**
Developing HACCP Records	**13.7 Hours**	**5 Hours**	**2 Hours**	**0.1 to 300 Hours**	**27.9**	**548**
Sanitation Procedures & Records	**13.3 Hours**	**5 Hours**	**1 Hour**	**0 to 300 Hours**	**27.4**	**545**

The responses to this question were similar to the results of the time estimates reported in earlier survey questions. The mean of the responses to Survey question 9 asking firms to estimate how much time the company spent developing the HACCP plan was 68.7 hours. If we add the means for the estimates of the specific components of the HACCP plan reported in Survey question 11, the total number of hours was 73.5. The similarity between these two arithmetic means from two separate questions would seem to indicate that the responses received were reliable and realistic. It also indicates that the components of the FDA regulation that relate to sanitation were included in these estimates. Overall, the most time was devoted to the development of the HACCP plan,

followed by the Hazard Analysis. Survey respondents appeared to have devoted an approximately equal amount of time to the development of HACCP records and Sanitation procedures and records. Since the primary focus of the FDA regulation and the training program was HACCP, it appears that less time was devoted to sanitation. This is consistent with the observations made in the inspections conducted during the first two years after the new FDA regulation became effective, and would seem to re-enforce the need for additional training and attention to sanitation issues for many firms.

Hourly Wage of HACCP Plan Developers

Firms that indicated that they had developed their own HACCP plan were asked to estimate the average hourly wage for those employees who were involved in the development of the firm's HACCP plan. The data for the 424 survey respondents who answered this question is shown in **Table 14**.

***Table 14. "A*verage hourly wage of the employees who were involved in developing and writing your company's HACCP plan."**

Mean	**$19.47**
Range	**$6 to $500 per Hour**
Median	**$15.00**
Standard Deviation	**31.3**
Number of Responses	**424**

The overall average hourly wage reported was $19.47 per hour with a median of $15 per hour. Based on this data we can estimate that for most seafood firms in the U.S., the average hourly wage of the individuals involved in HACCP plan development was between $15 and $20 per hour.

Table 15. Average hourly wage of employees involved in developing the HACCP plan compared to average annual sales.

Average Annual Sales	Mean	Median	Range	Standard Deviation	Number of Responses
$500,000 or less	**$18.61**	**$12.00**	**$0-$250**	**32.9**	**87**
$500,000 to $1 Million	**$15.87**	**$10.00**	**$0-150**	**22.9**	**39**
$1 to $3 Million	**$16.39**	**$15.00**	**$1-$75**	**10.3**	**83**
$3 to $5 Million	**$17.80**	**$16.00**	**$8-$50**	**8.8**	**33**
$5 to $10 Million	**$19.22**	**$15.00**	**$0-$200**	**25.4**	**56**
$10 to $20 Million	**$20.32**	**$19.00**	**$9-$75**	**11.9**	**44**
Greater than $20 Million	**$31.14**	**$20.00**	**$2-$500**	**71.2**	**46**

Table 15 compares the average hourly wage of HACCP plan developers to company size using average annual sales as an indicator of size. This data shows that the smallest firms with sales less than $500,000 paid an hourly wage higher than larger firms with sales up to $5 million. This suggests that for small businesses, owners rather than employees developed and wrote the firm's HACCP plan. For all other size firms there appeared to be a direct relationship between company

size and the average hourly wage of HACCP plan developers. The reported average hourly wage increased as company size increased, with the largest companies paying a significantly higher wage than the smallest. This data also tends to support the hypothesis that the largest companies had access to more highly trained or skilled employees, which was reflected in their average hourly wage.

Table 16 compares the mean average hourly wage reported for HACCP plan developers for the 13 states that comprise 70 percent of all of the survey responses. The relationship identified earlier, suggested that the amount of time spent developing the plan was related to the size of the companies that responded to the survey from each state does not appear to hold true for average hourly wages. Some states with a large proportion of very small firms such as Connecticut, Maine and Alaska reported an average hourly wage higher or similar to states like New Jersey and Massachusetts that had a high proportion of large firms. It seems likely that the major factor associated with the average hourly wages reported from each state relates to local labor costs and the availability of individuals qualified to develop and write the firm's HACCP plan.

Table 16. Average hourly wage of employees involved in writing the HACCP plan by state.

State	Mean	Median	Range	Standard Deviation	Number of Responses
New York	**$34.20**	**$18.00**	**$8-$500**	**73.2**	**56**
Connecticut	**$31.27**	**$15.00**	**$9-$200**	**51.8**	**13**
California	**$21.77**	**$20.00**	**$6-$100**	**15.4**	**32**
Maine	**$19.25**	**$12.00**	**$0-$200**	**35.9**	**28**
New Jersey	**$19.23**	**$20.00**	**$4-$35**	**8.9**	**13**
Alaska	**$18.26**	**$18.75**	**$10-$25**	**4.6**	**18**
Massachusetts	**$16.94**	**$15.00**	**$8-$27**	**5.4**	**17**
Louisiana	**$15.83**	**$10.00**	**$5-$65**	**13.5**	**33**
Texas	**$15.01**	**$15.00**	**$7-$30**	**6.3**	**20**
Maryland	**$14.77**	**$12.00**	**$0-$30**	**8.5**	**15**
Washington	**$14.31**	**$15.00**	**$8-$20**	**4.8**	**16**
Florida	**$13.89**	**$12.50**	**$6-$30**	**6.2**	**29**
North Carolina	**$11.92**	**$10.00**	**$0-$25**	**6.5**	**13**

HACCP Plan Development Costs

The responses related to both the number of hours involved in developing the HACCP plan and the hourly wage of employees who developed the plan covered a wide range. This variation is not unexpected, however, if the diversity of companies that returned a survey is considered. There were a large number of small firms who were likely to spend less time and have a lower cost as compared to larger firms who may have had to devote considerably more time to HACCP plan development. Costs were also likely to vary depending on firm size and the level of expertise within the firm that was used in HACCP plan development. When company owners and management were directly involved in the HACCP plan development, estimates of the hourly wage was likely to be higher than if production employees were assigned responsibility to develop the HACCP plan. These results indicate that companies chose a variety of strategies to

develop their plans. On average most companies spent approximately 69 hours developing their HACCP plans with a median of 30 hours. The maximum amount of time reported was 1,200 hours while the minimum was one half-hour. The mean hourly wage for the company employees who developed the HACCP plan was $19.47 per hour with a median of $15 per hour. The hourly wage reported for HACCP plan developers ranged from $6 to $500 per hour.

These survey results could be used to develop a rough estimate of the cost of developing a HACCP plan. If the calculated means were used to estimate cost, the average cost of developing a HACCP plan for the firms who returned this survey was 68.7 hours times $19.47 per hour for a total cost of $1,338.

Training costs should also be considered in an estimate of the cost of developing a HACCP plan. The training course that these individuals attended was three days in length for a total of 24 hours (8 hours/day x 3 days). This estimate is reasonable even though the third day of the course was frequently only 6 hours in length if the time spent on travel, registration and other activities is also considered. If the 24 hours spent on training is multiplied by the average reported hourly wage of those who developed the HACCP plan; the cost of training would be 24 x $19.47 or $467. Training course registration fees should also be included. Although registration fees varied across the country, for this example we will use an estimate of $100 for the registration fee. Total training costs could be estimated to be $567 per firm ($467+$100), for each individual who attended training. This cost does not include travel, lodging or other incidental costs that cannot be easily estimated, and were likely to have varied greatly for individual firms.

If training costs are added to the mean cost of developing a HACCP plan reported by the survey respondents, **we can estimate the total cost of developing a HACCP plan per firm to be approximately $1,905 ($1,338 for HACCP plan development + $567 for training for each individual who completed the training course).** HACCP plan development costs may have been significantly less for some smaller firms and significantly higher for larger firms or firms who conduct complicated processing procedures. However, an average cost estimate of approximately $2,000 seems to reflect a reasonable average considering the variety of firms and the large number of responses to these questions that were received.

Table 17. Total cost of HACCP development by average annual sales.

Average Annual Sales	Avg. Hours	Avg. Hourly Wage	Cost of Developing HACCP Plan	Training Cost*	Total Cost of HACCP Plan Development	Total Cost as Percent of Annual Sales
$500,000 or less	**27.7**	**$18.61**	**$ 516**	**$547**	**$1,063**	**0.2%**
$500,000-1 Million	**58.6**	**$15.87**	**$ 930**	**$481**	**$1,411**	**0.1%**
$1 to $3 Million	**63.6**	**$16.39**	**$1,042**	**$493**	**$1,535**	**0.05%**
$3 to $5 Million	**74.9**	**$17.80**	**$1,333**	**$527**	**$1,860**	**0.04%**
$5 to $10 Million	**95.3**	**$19.22**	**$1,832**	**$561**	**$2,393**	**0.02%**
$10 to $20 Million	**164.7**	**$20.32**	**$3,347**	**$588**	**$3,935**	**0.03%**
> $20 Million	**106.4**	**$31.14**	**$3,313**	**$847**	**$4,160**	**0.02%**

*Training Costs = 24 hours x average hourly wage + $100 registration fee

Table 17 compares total costs of HACCP plan development calculated as described above to company size using average annual sales as an indicator of company size. This data shows that the total cost of plan development increased as annual sales or company size increased from a low of $1,063 for the smallest companies as compared to four times as much or $4,160 for the largest companies. These costs can be explained by the reported increase in both the time devoted to HACCP plan development and the average hourly wage of plan developers, both of which increased progressively with company size. The estimates of HACCP plan development costs for the smallest firms, who responded to this survey, $1,063 was similar to the cost estimates made by FDA of $1,000 per firm in the Preamble to the HACCP regulation.

One of the significant impacts, however, is the relative cost burden of HACCP plan development. An indication of relative cost burden was estimated by expressing total costs as a percentage of average annual sales. While the dollar cost for the smallest companies was approximately ¼ the dollar cost for the largest, the total cost as a percentage of annual sales was 10 times higher for the smallest companies as compared to the largest. It can be expected that this relative cost would have a significantly greater financial impact on the smallest companies as compared to the largest.

Table 18. Total costs of HACCP plan development by state.

State	Average Hours	Average Hourly Wage	HACCP Plan Development Cost	Training Cost	Total Cost of HACCP Plan Development
New York	**60.8**	**$34.20**	**$2,079**	**$921**	**$3,000**
California	**96.3**	**$21.77**	**$2,096**	**$622**	**$2,718**
New Jersey	**82.1**	**$19.23**	**$1,579**	**$562**	**$2,141**
Texas	**107.9**	**$15.01**	**$1,620**	**$460**	**$2,080**
Alaska	**82.4**	**$18.26**	**$1,505**	**$538**	**$2,043**
Connecticut	**31.6**	**$31.27**	**$ 988**	**$850**	**$1,838**
Washington	**91.9**	**$14.31**	**$1,315**	**$443**	**$1,758**
Louisiana	**64.0**	**$15.83**	**$1,013**	**$480**	**$1,493**
Massachusetts	**48.1**	**$16.94**	**$ 815**	**$507**	**$1,322**
Maine	**31.3**	**$19.25**	**$ 603**	**$562**	**$1,165**
Florida	**52.1**	**$13.89**	**$ 724**	**$433**	**$1,157**
North Carolina	**41.8**	**$11.92**	**$ 498**	**$386**	**$ 884**
Maryland	**27.0**	**$14.77**	**$ 399**	**$454**	**$ 853**

The total cost of HACCP plan development varied considerably by state. The highest cost, $3,000 reported by New York firms, was 3.5 times higher than the lowest costs, $853, reported by Maryland firms. The overall cost for HACCP plan development was highest in the New York-New Jersey-Connecticut area, the West Coast – California, Alaska and Washington, and in Texas. The lowest costs were in the Southeastern states of Florida, North Carolina and Maryland. The reported variations in costs from state to state are likely to be a function of the size of firms that responded to this survey in each state and labor costs as reflected in the average hourly wage. States like California, New Jersey, and New York who had the greatest number of large firms also had the highest cost for HACCP plan development. Likewise states that tended to report a higher average hourly wage also tended to have a higher overall cost estimate, except for

states like Maine and Massachusetts whose average number of hours devoted to HACCP plan development were lower than the national average.

Comparison to FDA Cost Estimates

In the regulatory cost analysis presented in the Preamble to the FDA regulation (*Federal Register, Volume 60, Number 242, December 18, 1995*), the FDA estimated that the portion of the regulation related to HACCP plan development would take 16 hours per firm. The average number of hours reported in this survey was 68.7, or 4.3 times higher than the FDA estimate. It was unclear if sanitation records were included in the FDA estimate. However, if we only use the mean number of hours reported in **Table 13** for conducting the Hazard Analysis and developing the HACCP plan and monitoring records, the total is 60.2 hours. This estimate (without sanitation records) is still 3.8 times higher than the FDA estimate for HACCP plan development. There are a variety of potential reasons why the reported estimates were significantly higher. For wholesalers, the FDA may have underestimated the complexity of many businesses. Most full service wholesalers handle a wide variety of fish and shellfish species and product forms. For example, it was not uncommon for wholesalers in the New York City area to consider fifty to one hundred different species and/or products in their hazard analysis, develop product groups that have the same hazards and controls, and then develop three to four different HACCP plans for each of these groups. The process of completing a hazard analysis and developing a HACCP plan took considerably longer to complete than FDA envisioned. Many in the seafood industry also had little experience with the process used to develop a HACCP system, and had some difficulty developing, writing, and implementing their HACCP plan. The data from this survey shows that even the smallest firms reported that they spent an average of 27 to 30 hours (almost twice the FDA estimate) developing their HACCP system. The largest processors reported spending an average of 185 hours developing their HACCP system, which was 11.5 times higher than the FDA estimate.

FDA estimates of the cost of "HACCP Plan Refinement" reported in the Preamble to the Seafood HACCP Regulation was 16 hours billed at $15 per hour for a total cost of $240. The mean cost calculated from the data received in this survey, $1,338, was approximately 5.5 times higher than the FDA estimate of $240. The estimated cost of training for survey respondents, $567, is somewhat lower than the estimate for training of $760 given by FDA in the cost projections for HACCP found in the Preamble to the regulation. The total average cost of HACCP plan development and training calculated from these survey results was $1,905. This estimate is 1.9 times higher than the combined FDA estimate of $1,000 for training and HACCP plan refinement published in the Preamble to the FDA seafood HACCP regulation. The FDA cost estimates were similar to the average costs reported from seafood firms in North Carolina and Florida, but were significantly lower than the average costs reported in New York, New Jersey, California, Texas and Alaska, all of which were higher than $2,000.

Investments and Practice Changes Made to Comply with the HACCP Requirements of the FDA Regulation

A series of questions were included in the survey to evaluate the investments made by seafood firms in equipment and supplies as well as changes made in product handling or processing procedures as a result of efforts to comply with specific HACCP requirements of the FDA

seafood HACCP regulation. A separate series of questions was developed for both the **HACCP** and **Sanitation** components of the regulation.

HACCP Implementation Costs

Table 19. Amount of money reported to have been invested in equipment to meet the HACCP requirements of the FDA regulation.

Mean	**$15,077**
Median	**$ 1,500**
Range	**$0 to 750,000**
Standard Deviation	**53888**
Number of Responses	**501**

Table 19 summarizes the responses to the question that asked firms to **estimate the amount of money that was invested in equipment to meet the HACCP requirements of the FDA regulation.** The mean of the 501 responses that were received suggested that seafood firms in the U.S. spent slightly more than $15,000 on equipment to comply with the HACCP requirements of the FDA regulation. There was a considerable range from small firms that spent virtually nothing to several firms that spent from one-half to three-quarters of a million dollars. It is difficult to determine exactly how much of this investment was directly related to the requirements of the HACCP regulation. What is significant, however, is that either directly or indirectly the regulation stimulated many firms to make substantial investments to upgrade their facilities.

Table 20. Amount of money invested to meet the HACCP requirements of the FDA regulation for all companies who reported their average annual sales.

Average Annual Sales	Mean Cost	Mean Cost as a % of Annual Sales	Median	Range	Number of Responses
$500,000 or less	**$4,847**	**1.0%**	**$500**	**$0-100,000**	**146**
$500,000 to $1 Million	**$7,590**	**0.8%**	**$550**	**$0-165,000**	**44**
$1 to $3 Million	**$12,012**	**0.4%**	**$3,200**	**$0-200,000**	**95**
$3 to $5 Million	**$12,250**	**0.2%**	**$2,000**	**$0-70,000**	**25**
$5 to $10 Million	**$35,562**	**0.4%**	**$3,000**	**$0-500,000**	**58**
$10 to $20 Million	**$21,395**	**0.1%**	**$3,000**	**$0-275,000**	**47**
> $20 Million	**$22,783**	**0.1%**	**$7,500**	**$0-200,000**	**47**

More accurate estimates of the amount of money invested to meet the HACCP requirements of the FDA regulation can be obtained if reported costs are broken down by company size. Smaller firms with less than $1 million in annual sales reported costs in the $5,000 to $10,000 range. Mid sized firms reported costs that were somewhat higher except for the firms with $5-10 million in annual sales for whom the mean expenditure was over $35,000. The largest firms reported investments greater than $20,000 on average to meet the HACCP requirements. This data appears to indicate that the relative cost of complying with this regulation in proportion to

overall company revenue was significantly higher for smaller firms. If we compare cost to sales for the smallest firms (sales less than $1 Million) the reported cost was approximately 1 percent of annual sales. For the largest firms (sales greater than $20 Million), the average reported cost was approximately 0.1 percent of annual sales. This would suggest that the relative cost burden for expenditures to meet the HACCP requirements for the smallest firms was as much as 10 times greater for the smallest firms than the relative cost burden for the largest firms.

Table 21. Amount of money invested to meet the HACCP requirements of the FDA regulation for all wholesalers who reported their average annual sales.

Average Annual Sales	Mean Cost	Mean Cost as a % of Annual Sales	Median	Range	Number of Responses
$500,000 or less	$5,972	1.0%	$ 600	$0-100,000	62
$500,000 to $1 Million	$9,244	0.9%	$ 500	$0-165,000	29
$1 to $3 Million	$14,680	0.5%	$3,500	$0-200,000	64
$3 to $5 Million	$12,283	0.2%	$ 500	$0-70,000	15
$5 to $10 Million	$41,042	0.4%	$3,000	$0-500,000	37
$10 to $20 Million	$18,351	0.1%	$3,000	$0-275,000	31
> $20 Million	$25,348	0.1%	$7,500	$0-200,000	29

Table 22. Amount of money invested to meet the HACCP requirements of the FDA regulation for all processors who reported their average annual sales.

Average Annual Sales	Mean Cost	Mean Cost as a % of Annual Sales	Median	Range	Number of Responses
$500,000 or less	$6,179	1.0%	$1,200	$0-100,000	54
$500,000 to $1 Million	$20,478	2.0%	$2,000	$0-165,000	9
$1 to $3 Million	$15,370	0.5%	$8,000	$0-100,000	29
$3 to $5 Million	$10,743	0.2%	$ 4,500	$400-70,000	14
$5 to $10 Million	$45,939	0.5%	$ 6,000	$0-500,000	23
$10 to $20 Million	$16,053	0.1%	$ 5,000	$0-100,000	18
> $20 Million	$19,794	0.1%	$10,000	$0-150,000	17

Tables 21 and 22 summarize the reported expenditures on HACCP requirements of the FDA regulation made by the two largest sectors of the seafood industry that provided the majority of responses to this survey, wholesalers and processors. For both industry sectors expenditures increased with company size. For wholesalers, costs increased proportionately with company size except for mid-sized firms with $5-10 million in annual sales that reported costs significantly higher than firms with annual sales twice as high. Overall costs for wholesalers in most categories were slightly lower than those reported for processors in the same size category. The relative cost burden expressed as a percentage of annual sales was similar for wholesalers and processors in most size categories. Again the relative cost burden for the smallest companies in both sectors was approximately 10 times greater than for the largest. This burden was even higher for small processors with average annual sales between $500,000 and $1 million- in

which the reported relative cost of HACCP expenditures was 2 percent of sales which was 20 times higher than the relative cost burden for the largest processors which was 0.1 percent of annual sales.

Table 23. Money invested to meet the HACCP requirements of the FDA regulation by state.

State	Mean	Median	Range	Standard Deviation	Number of Responses
California	**$28,498**	**$8,000**	**$0-275,000**	**54419**	**36**
New York	**$28,167**	**$3,000**	**$0-750,000**	**99895**	**63**
Texas	**$22,756**	**$2,500**	**$0-250,000**	**52937**	**25**
Louisiana	**$14,277**	**$2,500**	**$0-115,000**	**23356**	**36**
Maine	**$13,726**	**$2,000**	**$0-125,000**	**24542**	**41**
Massachusetts	**$13,113**	**$5,000**	**$0-65,000**	**21387**	**16**
New Jersey	**$11,110**	**$3,000**	**$0-45,000**	**14461**	**14**
Florida	**$ 9,619**	**$1,000**	**$0-165,000**	**32080**	**26**
Connecticut	**$ 7,118**	**$ 550**	**$0-30,000**	**11257**	**14**
Maryland	**$ 4,970**	**$1,000**	**$0-25,000**	**7240**	**20**
Washington	**$ 3,898**	**$2,200**	**$20-12,000**	**4563**	**14**
Alaska	**$ 2,255**	**$1,000**	**$0-10,000**	**2828**	**27**
North Carolina	**$ 2,214**	**$ 500**	**$20-15,000**	**4648**	**15**

Table 23 summarizes the HACCP requirements expenditure data reported by the 13 states that represented 70 percent of the survey responses received from seafood firms in the United States. The highest expenditures were reported from firms located in California, New York, and Texas. The lowest expenditures were reported in North Carolina, Alaska, and Washington. The expenditures reported by firms in California were the highest and were approximately 13 times greater than the expenditures reported by firms in North Carolina, which were the lowest. In general those states from which a greater number of large firms returned survey questionnaires reported higher average expenditures on equipment to meet the HACCP requirements and the states with more small firms tended to report lower average expenditures. Reported expenditures are also likely to vary because of other factors such as regional costs of equipment and services, and the condition of existing industry infrastructure in urban and rural areas.

HACCP Equipment Purchases

The HACCP Implementation Survey also attempted to identify **how** the money invested to comply with the HACCP requirements of the FDA regulation was spent. Survey respondents were asked to report **what equipment did you purchase, upgrade or modify.** The survey questionnaire provided a list of 12 items that could be associated with HACCP type food safety controls, and firms were asked to check all of the items that they had purchased, upgraded or modified. Survey respondents were also given an opportunity to report other items not included in this list. **Table 24** summarizes the 611 industry responses to this question.

Table 24. Equipment purchased, modified, or upgraded to meet the HACCP requirements of the FDA regulation.

Thermometers	**487**
Coolers	**172**
Other Monitoring Devices	**165**
Product Test Kits	**149**
Ice Machines	**112**
Computers or Office Equipment	**112**
Shipping Containers	**106**
Truck Refrigeration Units	**92**
Laboratory Services	**90**
Delivery Trucks	**72**
New Processing Equipment	**51**
Display Units	**48**
Other	**91**
No Response Received	**133**

Other equipment items that were reported included: new tuna display; new grader; stainless steel tables; vacuum packing machine; two chillers; electric motor compressor; new scallop table; new packaging equipment; new freezer; wire, thermocouple, logic boards, and conduit; refrigeration machinery; kosher temperature truck; more paper; built a whole new room; sprayer; chiller; thermometer; new freezer system; a complete testing laboratory; vacuum pack overwrap; new recorders in smoke house; software for monitoring temperatures; filling equipment; metal detectors; new processing area; large ice chest for alligators; recording machines for cooking, cooler, freezer, canners, packers etc.; cutting boards; new grinder; new processing room; labeling devices; washer fans; new scales; vacuum sealer; had to build a new building; smoker probes; ovens for smoking; clam table; replaced and renewed process equipment and air conditioned plant in order to lower temperature; new cooling units for storage of products; Kem-Lite; packaging labeling for vacuum sealed ready-to-eat products; refrigeration unit; re-glassed and insulated fish hold; computers; file cabinets and office shelves.

It seems clear from these responses that the major investments made by the seafood industry to meet the HACCP requirements related to maintaining or monitoring product temperatures. The most frequently purchased item, thermometers, was relatively low cost, but these devices significantly improved a large number of firms' ability to monitor conditions in their operation. The other equipment most frequently purchased, upgraded or modified included items that were likely to require a substantial capital investment. These items included coolers, ice machines, delivery trucks and truck refrigeration units. Many of the other items listed in response to this question also indicated that new refrigeration units, freezers, compressors etc. were purchased to ensure that time-temperature critical control points could be met. For most seafood wholesalers, the most frequently encountered food safety hazards related to histamine development or pathogen growth in specific types of products. Control of these hazards requires that time-temperature relationships be analyzed and controlled. This message was effectively conveyed in HACCP training and the FDA guidance materials. The industry has made appropriate

investments in equipment to enhance their ability to maintain proper temperatures for their products both during storage and during shipping. This is likely to have a significant impact on both the safety and quality of seafood products available in the marketplace, and to be one of the most significant impacts of the seafood HACCP regulation.

Significant investments were also made in other monitoring devices, product test kits, and laboratory services. These investments were likely to relate directly to the monitoring of specific critical control points, to provide options for corrective actions, or for use with the verification component of the HACCP system. One firm reported that they installed a new complete product-testing laboratory for their operation. Several firms also reported that they built entirely new processing areas for their operation. This decision apparently occurred after they learned about the types of controls that they needed.

One could argue whether or not some of the equipment purchased was directly related to HACCP controls and the FDA seafood HACCP regulation. However, these firms did make the decision to make these investments as a result of their assessment of this regulation and their ability to operate efficiently and profitably under the conditions that the regulation imposed. Anecdotal evidence suggests that many firms who were considering equipment investments waited for several years until the FDA seafood HACCP regulation and guidance material was available. As either as a direct or indirect result of the FDA seafood HACCP regulation, seafood firms across the United States made substantial investments in equipment that will enhance their ability to control food safety hazards in their operation.

Operational Changes Made to Meet HACCP Requirements

The survey also attempted to identify what changes were made in seafood handling procedures and practices to meet the HACCP requirements of the FDA regulation. Survey respondents were provided with a list of seven choices of possible HACCP related changes that were likely to have occurred as a result of the application of HACCP principles to their operation. Respondents were also provided with an opportunity to identify other changes not provided. A summary of the 682 responses received to this question is provided in **Table 25**.

Table 25. Specific changes in operations and plant facilities made to meet the HACCP requirements of the FDA regulation.

494 – Use thermometers or other monitoring devices more frequently.

355 – Changed how you store products and monitor storage conditions.

341 – Changed the way you evaluate some or all products at receiving.

322 – Verified one or more processing procedures to control a food safety hazard.

233 – Use more ice during storage, display, and shipping to control product temperature.

156 – Use test kits or send samples out for laboratory analysis.

144 – Changed packing or shipping techniques for higher risk products.

113 – Other: Keep more complete records; changed my thinking about hazards and how I can prevent or control them; more employee training on HACCP issues; keeping logs on temperature control; control shipment of live products to prevent cross contamination; use more ice during processing; documenting and verifying the controls we already had; paperwork has quadrupled without improvements in control procedures; purchased a computer to manage temperature records; we did all of these things before HACCP; shut down operation until I could meet HACCP requirements; we keep records now but did not change the way we handle fish; watch the clock more closely and speed up procedures if necessary to get the product to the market; use tags on vessels for lot numbers; we already had these procedures in place; putting everything in writing; make customers aware that product complies before leaving the plant; nothing changed we already had all these procedures in place; use more paper; now do record keeping analysis; built a new facility; new building was built with HACCP requirements in mind; proper record keeping for new charges; no changes; keep records of the obvious healthy procedures already in place; calibrate thermometers; all of the above were in use – we just started recording our processes; we have used USDC HACCP since 1994; train employees to keep better records; monitor temperatures of incoming product; started keeping records differently; built new processing room; no changes we were already in compliance; use a certified boat; wrote formal procedure for receiving; standardized daily inspection procedures and created better ones; record keeping; more paper work.

The reported changes in product handling and operations management are consistent with the reported equipment investments. The industry has appropriately focused attention on improving their system of time and temperature controls to ensure product safety, and has made the investment in both the time and equipment needed to achieve improved performance. These changes have occurred at processing steps such as receiving, storage, and shipping that are most likely to be critical control points in a seafood wholesale operation. Both processors and wholesalers have changed the way that they keep records which should help them to more effectively control their operation and make informed decisions as changes are needed. These behavior changes along with the appropriate investment in the tools needed to make them that were documented in this survey are likely to result in a significant improvement in industry performance in maintaining both the safety and quality of seafood products available in the marketplace.

Investments and Practice Changes Made to Comply with the Sanitation Requirements of the FDA Regulation

The FDA seafood HACCP regulation included specific requirements related to eight areas of sanitation in addition to the requirements related to the development and implementation of each firm's HACCP plan. FDA identified these eight areas of sanitation as being the areas of the existing Good Manufacturing Practice (GMP) regulations that should receive special attention. As a result, many firms needed to evaluate both how to effectively comply with the new sanitation requirements in the HACCP regulation as well as existing requirements of current Good Manufacturing Practices (21CFR Part 110). This survey attempted to document the

investments and changes that were made as a result of these requirements. Specific questions similar to those asked about HACCP implementation were included for sanitation.

Cost of Sanitation Requirements

The survey specifically asked respondents to "**estimate how much money your company has invested in new equipment or services to meet the sanitation requirements of the GMPs and/or the HACCP regulation."** The results of the survey responses to this question are summarized in **Table 26**.

Table 26. Money invested in equipment or services to meet the sanitation requirements of the GMPs and/or HACCP regulation.

Mean	**$10,190**
Median	**$ 1,000**
Range	**$0 to $500,000**
Standard Deviation	**37983**
Number of Responses	**502**

Based on 502 survey responses, seafood firms invested an average of $10,190 in equipment or services to ensure that they could comply with sanitation regulations. There was a considerable range of responses from $0 to $500,000, which most likely reflected the condition of individual facilities. Although it is difficult to use this mean as a reflection of cost for each individual firm, it does indicate that the industry did make significant investments to improve their facilities and sanitation operations. More reliable cost estimates can be obtained by comparing survey responses on reported expenditures to company size.

Table 27. Money invested in equipment and services to meet sanitation requirements of the GMPs and/or HACCP regulation in relation to average annual sales.

Average Annual Sales	Mean Cost	Mean Cost as a % of Annual Sales	Median	Range	Number of Responses
$500,000 or less	**$3,650**	**0.7%**	**$ 500**	**$0-70,000**	**161**
$500,00-$1 Million	**$7,754**	**0.8%**	**$ 300**	**$0-165,000**	**38**
$1 to $3 Million	**$7,852**	**0.3%**	**$1,400**	**$0-200,000**	**87**
$3 to $5 Million	**$10,634**	**0.2%**	**$1,000**	**$0-140,000**	**32**
$5 to $10 Million	**$26,690**	**0.3%**	**$2,500**	**$0-500,000**	**59**
$10 to $20 Million	**$16,805**	**0.1%**	**$ 500**	**$0-100,000**	**45**
> $20 Million	**$14,346**	**0.07%**	**$7,000**	**$0-200,000**	**40**

Table 27 summarizes responses to the question related to money invested in sanitation equipment or services by annual sales. The average expenditures reported varied by company size. The smallest firms spent on average between $3,500 and $10,000 on sanitation or GMP requirements. Medium sized companies with annual sales between $5-10 million reported spending the most on sanitation with a mean greater than $25,000. The largest firms reported

spending over $15,000 on sanitation or GMP requirements. As with the reported HACCP expenditures, the relative cost burden can be expressed as the percent that mean sanitation expenditures were in comparison to annual sales. For sanitation as with HACCP, the relative cost burden of the smallest firms was approximately 7 to 8 times higher than that for the largest firms.

Based on the data related to mean expenditures, it appears that firms spent approximately 1.5 times more on HACCP requirements than was invested in sanitation equipment and services. There may be a variety of reasons for this observation. Sanitation expenditures may have been focused on a more limited scope of issues directly related to the eight areas identified in the FDA regulation. Specific sanitation improvements, equipment or supplies were also likely to cost less than the types of investments made in coolers, ice machines, processing equipment, laboratory services, test kits, and refrigerated trucks that were identified as being associated with HACCP requirements.

Table 28. Amount of money invested to meet the Sanitation requirements of the FDA regulation for all wholesalers who reported their average annual sales.

Average Annual Sales	Mean Cost	Mean Cost as a % of Annual Sales	Median	Range	Number of Responses
$500,000 or less	$ 5,050	1.0%	$500	$0-70,000	65
$500,000-$1 Million	$10,244	1.0%	$400	$0-165,000	24
$1 to $3 Million	$ 9,295	0.3%	$2,000	$0-200,000	59
$3 to $5 Million	$11,528	0.2%	$1,000	$0-140,000	22
$5 to $10 Million	$39,132	0.4%	$2,500	$0-500,000	37
$10 to $20 Million	$11,620	0.08%	$3,000	$0-100,000	29
> $20 Million	$11,797	0.06%	$8,000	$0-55,000	25

Table 29. Amount of money invested to meet the Sanitation requirements of the FDA regulation for all processors who reported their average annual sales.

Average Annual Sales	Mean Cost	Mean Cost as % of Annual Sales	Median	Range	Number of Responses
$500,000 or less	$ 3,863	0.8%	$ 800	$0-40,000	61
$500,000-$1 Million	$16,900	1.7%	$ 300	$0-165,000	10
$1 to $3 Million	$ 7,521	0.3%	$2,000	$0-40,000	28
$3 to $5 Million	$ 8,228	0.2%	$2,000	$0-70,000	16
$5 to $10 Million	$29,608	0.3%	$5,000	$0-500,000	24
$10 to $20 Million	$19,539	0.1%	$ 250	$0-100,000	19
> $20 Million	$ 7,977	0.04%	$10,000	$0-20,000	13

Tables 28 and 29 show costs for the two industry sectors that made up the majority of the firms who responded to the survey questionnaire, wholesalers and processors. For most sizes of firms wholesalers reported slightly higher cost than processors with the same annual sales. This was

true except for small processors with annual sales between $500,000 and $1 million whose reported costs were significantly higher than the same size wholesalers and even as high or higher than the largest processors. This same trend was observed with HACCP expenditures for processors with annual sales between $500,000 and $1 million. Apparently these firms needed to make significant investments in both processing equipment and facilities and infrastructure to meet the HACCP and sanitation requirements of the FDA regulation. The relative cost burden for sanitation expenditures expressed as a percentage of average annual sales for wholesalers was approximately 16 times higher for the smallest firms as compared to the largest. For processors the relative cost burden was at least 20 times higher for the smallest firms as compared to the largest.

Table 30. Money invested to meet the Sanitation requirements of the FDA regulation by state.

State	Mean	Median	Range	Standard Deviation	Number of Responses
New Jersey	**$23,498**	**$2,000**	**$0-200,000**	**54314**	**13**
California	**$18,543**	**$3,000**	**$0-200,000**	**37945**	**37**
Texas	**$13,773**	**$2,000**	**$0-140,000**	**35330**	**22**
Florida	**$ 9,978**	**$ 300**	**$0-165,000**	**32125**	**28**
Maine	**$ 9,816**	**$1,500**	**$0-125,000**	**21640**	**46**
Massachusetts	**$ 9,700**	**$2,000**	**$0-55,000**	**16806**	**18**
New York	**$ 8,697**	**$2,000**	**$0-70,000**	**15960**	**52**
Maryland	**$ 6,987**	**$2,000**	**$0-50,000**	**12136**	**19**
Connecticut	**$ 5,303**	**$ 500**	**$0-35,000**	**10966**	**14**
Louisiana	**$ 3,946**	**$1,000**	**$0-46,000**	**8521**	**36**
Alaska	**$ 2,467**	**$ 500**	**$0-18,000**	**4195**	**31**
Washington	**$ 1,977**	**$ 650**	**$0-8,000**	**2815**	**15**
North Carolina	**$ 629**	**$ 100**	**$0-3,000**	**947**	**15**

The variation in the average sanitation costs reported by firms in the 13 states that represented 70 percent of all of the survey responses was large. The highest cost, $23,498, was the average reported by the 13 firms who responded to this question from New Jersey, and the lowest costs, $629, was the average reported by the 15 firms who responded to this question from North Carolina. Factors that cannot be readily determined are likely to have influenced the cost estimates from these two states that were significantly different from the costs reported by the other states. If we compare costs reported by California to those reported by Washington, the higher reported costs in California were approximately nine times higher than the second lowest reported costs in Washington. As with the reported HACCP costs part of the explanation for these cost differences is likely to be related to the size firms who responded to the survey questionnaire from each state. California and New Jersey had a significant number of medium to large firms who responded to the survey while most of the firms from North Carolina, Washington and Alaska were small firms. Regional differences in costs such as equipment and labor were also likely to be reflected in the mean costs reported from these states.

Operational Changes Made to Meet Sanitation Requirements

The survey also attempted to identify what sanitation equipment or services were purchased, upgraded or modified. Survey respondents were asked to check all items that applied to them from a list of 14 types of equipment, supplies, or services associated with current sanitation requirements. Respondents also had an opportunity to identify other equipment or services that were not included in this list. The number of responses for each item received from the 556 survey respondents that answered this question is summarized in **Table 31**.

Table 31. Number of survey respondents who purchased, upgraded, or modified specific sanitation equipment, supplies or services.

260 – New sanitizer or cleaner
242 – Employee supplies (hats, gloves etc.)
224 – Hand wash stations
194 – Hand sanitizer
169 – Wall or ceiling surfaces
154 – Floor surfaces
146 – Light fixtures
146 – Pest control
139 – Power washers
125 – Cutting boards
115 – Triple or Double Sinks
73 – Cutting Tables
30 – Display Units
54 – Other Equipment
188 – Did not respond to this question

Other responses included: boot and glove dips, drains, foot baths, forklifts, boat storage and work surfaces; cooler walls or surfaces; water treatment plant; pipe covers; none all were in place before; outside cleaning service; already had what we needed; modified a clean up room; drainage system improvement; dish washing equipment; new boiler; air curtains; built restroom close to processing room; already in compliance; foamer; continue to practice good GMPs; I am a one person operation and I already sanitized before HACCP; I was told to fill small holes from toe nailing former walls; had to build plumbing room outside of house; purchased new pressure washer; none always kept the place clean; labeled everything including the toilet paper; took GMP training classes; purchased fly fans; enhanced documentation of SSOPs; installed foaming cleaners; monitored SSOP reporting; wrote formal procedures for sanitation; changed sanitation documentation procedures.

The survey responses show that seafood firms invested in a wide variety of sanitation supplies or equipment depending on the individual needs of each operation. The use of sanitizers, cleaners, and employee supplies were re-evaluated by many firms. A substantial number of firms also made investments in fixed equipment such as hand wash stations, sinks, tables, and mobile equipment such as cutting boards, knives or other utensils. Investments made in these items were most likely to replace equipment that was either in poor condition or not made of appropriate materials. Firms also made substantial investments in infrastructure such as floors, walls, ceilings, and light fixtures to ensure compliance with sanitation or GMP requirements. A number of firms also appeared to re-evaluate their existing programs or services for pest control.

The survey questionnaire was also designed to identify the changes in facilities, practices or behavior related to sanitation that were made in response to training and/or requirements of the HACCP or GMP regulations. Respondents were asked to report "**what changes have you made**

in your plant facility to meet the Sanitation and Good Manufacturing Practice requirements." A list of six likely changes associated with sanitation was included and respondents were asked to check all that apply. An opportunity to identify other changes not included in the list was also provided. The results of the 618 survey responses to this question are summarized in **Table 32**.

Table 32. Number of survey respondents who reported making specific changes in their plant facility to meet the sanitation and GMP requirements.

354 – Changed cleaning and sanitizing procedures.

339 – Conducted employee sanitation training programs (formal or informal)

301 – Purchased, modified or upgraded physical structures (floors, wall, ceilings, drains)

287 – Purchased or upgraded equipment such as sinks, hand wash stations etc.

193 – Changed company policies regarding employee health and hygiene.

181 – Changed or modified support services such as pest control, garbage removal etc.

126 – Did not respond to this question

70 – Other including: updated record keeping system and procedures; set up a timetable to monitor frequency of cleaning procedures; had a formal employee in-service training program; all employees were HACCP trained; two hours with paper work – power washing bins one hour- and wooden crates not approved for processing anymore; copying next weeks blank forms; sanitation is continuous; increased work time by 15 percent on a 24 hour cycle; sanitation we do thoroughly regardless of FDA; spend 20 hours per week processing – five hours per week sanitizing – and three hours per week keeping records; monthly clean and inspect shed; total 15 hours per week spent; 10 hours administrative work in general has been added; sanitation is integrated into the QC programs.

Survey responses indicate that a number of important activities and changes related to sanitation practices have occurred as a result of the training effort and the requirements of the FDA regulation. Most companies appear to have re-evaluated their cleaning and sanitizing practices and made changes that are likely to result in more effective procedures. The amount of effort devoted to formal and informal training activities for employees is also likely to result in greater awareness and compliance with appropriate personal hygiene and food handling practices. While these behavior changes can take time to achieve, it is significant that a large number of firms have recognized and emphasized the importance of training and its potential positive impact on employee behavior. Many firms made substantial investments in improving plant infrastructure such as walls, ceilings, floors, and drains, and equipment such as hand wash stations and cleaning aids. During the first year of HACCP based inspections, regulators identified a large number of deficiencies in sanitation requirements of the HACCP regulation. Results from this survey would indicate that significant improvements have been made by the industry, and many of the observed deficiencies are likely to be related to monitoring and record keeping

requirements rather than inadequate practices. Inspections are generally designed to identify deficiencies, and are not structured to identify or recognize the type of improvements in infrastructure and equipment that were reported in this survey.

Resources Devoted to Routine Requirements of the HACCP Regulation

Two survey questions were included to obtain an estimate of the amount of time that firms are devoting to the routine requirements of the HACCP regulation and the type of activities that require the most time. Survey respondents were specifically asked to "**estimate the number of hours per week that are devoted to the routine requirements of the FDA regulation including the HACCP plan and sanitation requirements."** Survey responses are summarized in **Table 33**.

Table 33. Number of hours per week devoted to the routine HACCP and Sanitation requirements of the FDA regulation.

Mean	**14.1 Hours**
Median	**10.0 Hours**
Mode	**10.0 Hours**
Range	**0.5 to 300 Hours**
Standard Deviation	**22.9**
Number of Responses	**565**

The average amount of time to conduct the routine HACCP and sanitation requirements of the HACCP regulation was reported to be approximately 14 hours per week with a range from ½ hour to 300 hours. The amount of time reported varied depending on the size of the firm and the complexity of the operations conducted. This reported mean was used to calculate the average annual cost of routine HACCP and sanitation requirements by multiplying the weekly average of 14.1 hours by 52 since most firms are not likely to be seasonal operations and are open for business all year. To determine hourly costs both the mean and the median hourly wage reported for HACCP plan development was used. Average annual costs for meeting the routine requirements of this regulation could be estimated to be 728 hours (14 x 52) per year multiplied by $19.47 per hour for a total cost of $14,174 per year. If the median average hourly wage of $15 per hour is used, the average annual cost would be 728 hours times $15 per hour for a total cost of $10,920. Based on this data, the average annual cost of the routine requirements of the FDA HACCP regulation could be estimated with a high degree of confidence to be between $10,000 and $15,000 per year on average for seafood firms in the U.S.

Table 34. Estimated annual cost to meet the routine HACCP requirements of the FDA regulation for all firms who reported their average annual sales.

Average Annual Sales	Mean hours per week	Mean hourly wage	Average Annual Cost	Annual Cost as a % of Annual Sales
$500,000 or less	**8.2**	**$18.61**	**$ 7,935**	**1.6%**
$500,000 to $1 Million	**11.8**	**$15.87**	**$ 9,738**	**1.0%**
$1 to $3 Million	**11.6**	**$16.39**	**$ 9,886**	**0.3%**
$3 to $5 Million	**14.3**	**$17.80**	**$13,236**	**0.3%**
$5 to $10 Million	**16.8**	**$19.22**	**$16,791**	**0.2%**
$10 to $20 Million	**17.2**	**$20.32**	**$18,174**	**0.1%**
Greater than $20 Million	**32.2**	**$31.14**	**$52,141**	**0.3%**

Table 34 shows the mean number of hours per week for routine HACCP requirements that were reported by companies of various sizes expressed in terms of average annual sales. This data shows that as company size increases so does the amount of time reported to meet the routine requirements of the seafood HACCP regulation. The largest firms reported that almost four times more time was spent on routine HACCP requirements as the smallest firms. Total annual cost of the routine HACCP requirements was calculated using the average time per week reported which was then multiplied by 52 weeks per year. The mean hourly wage for HACCP plan developers reported earlier was used to estimate cost per hour. Average annual costs for the routine HACCP requirements for the smallest firms averaged between $8,000 to $10,000 and over $50,000 for the largest firms. The total annual cost for the largest firms was approximately 6.5 times higher than for the smallest firms. The relative cost burden of routine HACCP requirements can be expressed in terms of annual cost as a percentage of total annual sales. The relative annual cost burden for the smallest firms is five times higher than the largest firms and eight to sixteen times higher than the cost for firms with sales between 5 and 20 million. This ongoing annual cost may be significant for many smaller firms especially when these costs represent 1.6 percent of their total annual sales.

Table 35. Estimated annual cost to meet the routine HACCP requirements of the FDA regulation for all <u>wholesalers</u> who reported their average annual sales.

Average Annual Sales	Mean hours per week	Mean hourly wage	Average Annual Cost	Annual Cost as a % of Annual Sales
$500,000 or less	**7.9**	**$19.59**	**$ 8,048**	**1.6%**
$500,000 to $1 Million	**12.1**	**$12.39**	**$ 7,796**	**0.8%**
$1 to $3 Million	**12.2**	**$15.31**	**$ 9,713**	**0.3%**
$3 to $5 Million	**14.5**	**$16.98**	**$12,803**	**0.3%**
$5 to $10 Million	**12.2**	**$20.38**	**$12,929**	**0.1%**
$10 to $20 Million	**15.3**	**$20.54**	**$16,342**	**0.1%**
> $20 Million	**25.9**	**$36.80**	**$49,562**	**0.2%**

Table 36. Estimated annual cost of the routine requirements of the FDA regulation for all processors who reported their average annual sales.

Average Annual Sales	Mean hours per week	Mean hourly wage	Average Annual Cost	Annual Cost as a % of Annual Sales
$500,000 or less	**9.6**	**$12.56**	**$6,270**	**1.3%**
$500,000 to $1 Million	**13.7**	**$12.65**	**$9,012**	**0.9%**
$1 to $3 Million	**12.6**	**$17.71**	**$11,604**	**0.4%**
$3 to $5 Million	**18.8**	**$18.34**	**$17,929**	**0.4%**
$5 to $10 Million	**29.1**	**$17.08**	**$25,845**	**0.3%**
$10 to $20 Million	**20.4**	**$19.53**	**$20,717**	**0.1%**
> $20 Million	**49.8**	**$22.31**	**$57,774**	**0.3%**

Tables 35 and 36 show the reported average annual costs of the routine requirements of the HACCP regulation for the two industry sectors that comprised the majority of survey responses that were received. The calculated average annual cost of routine HACCP requirements was higher for all sizes of processors as compared to wholesalers, except for the smallest firms with annual sales less than $500,000. Costs reported by the smallest wholesalers were higher than those reported for the smallest processors. The total annual cost for the largest wholesalers, $49,562, was approximately six times higher than the annual cost of $8,048 for the smallest wholesalers. This total cost differential was even higher for processors. The total annual cost for the largest processors was approximately nine times higher than for the smallest.

The calculated annual cost burden expressed as annual cost as a percent of average annual sales was highest for the smallest wholesalers, 1.6 percent of annual sales, and the smallest processors, 1.3 percent of annual sales. The annual cost burden for the smallest wholesalers was approximately eight times higher than the annual cost burden for the largest wholesalers. For processors, the relative annual cost burden for the smallest processors was four times greater than that for the largest processors. These annual costs could be significant for both small wholesalers and processors who are already operating on a small profit margin.

Table 37. Estimated Annual Cost to meet routine HACCP regulation requirements by state.

State	Mean Hours per Week	Mean Hourly Wage	Average Annual Cost
Texas	**34.9**	**$15.01**	**$27,240**
New Jersey	**25.8**	**$19.23**	**$25,799**
Florida	**22.4**	**$13.89**	**$16,179**
New York	**8.6**	**$34.20**	**$15,294**
Connecticut	**8.9**	**$31.27**	**$14,472**
California	**12.7**	**$21.77**	**$14,377**
Maine	**13.0**	**$19.25**	**$13,013**
Alaska	**12.7**	**$18.26**	**$12,059**
Massachusetts	**13.3**	**$16.94**	**$11,716**
Louisiana	**12.1**	**$15.83**	**$ 9,960**
Maryland	**12.0**	**$14.77**	**$ 9,216**
North Carolina	**10.6**	**$11.92**	**$ 6,570**
Washington	**6.2**	**$14.31**	**$ 4,614**

Table 37 shows the calculated annual cost of routine HACCP requirements reported for each of the 13 states that provided 70 percent of all the survey responses. Firms reporting the highest average annual costs, greater than $25,000, were from Texas and New Jersey. Other states that had a greater proportion of large companies who responded to this survey such as New York and California reported annual costs above the overall mean cost for all survey respondents. States like Maryland, North Carolina and Washington that had a large percentage of small firms who responded to the survey had the lowest calculated annual cost. The highest calculated annual cost, $27,240 for Texas, was approximately six times higher than the lowest reported annual cost of $4,614 for Washington. As with other cost estimates for these states, the variability in calculated costs is likely to be related to company size, type and diversity of business activities, and local labor costs.

Comparison to FDA Cost Estimates

In the regulatory impact analysis in the Preamble to the seafood HACCP regulation (*Federal Register, Vol. 60, No. 242, 12/18/95*), FDA developed cost estimates for HACCP in small plants for the second year after the regulation was implemented that were used to estimate routine annual costs of HACCP. Two examples were provided one that did not include any GMP costs and another that did include GMP costs. The estimate for small plants that did not include GMP costs was $4,000 per year, and the estimate that included GMP costs was $9,900 per year. If these estimates are compared to the estimates calculated from this survey data, it appears as if the original FDA estimates may have been somewhat low. The mean annual cost of routine HACCP requirements reported from this survey data was $14,174. If we assume that the data gathered in this national survey included GMP costs, the national mean annual costs were approximately 1.4 times greater than the FDA estimate for small plants. There was also considerable variation in the reported annual costs when company size is considered. The smallest firms reported a mean annual cost of $7,935, which was close to the FDA estimate for firms with GMP costs. However, the largest firms reported annual costs of approximately $52,000, which is over five times higher than the FDA estimate. There was also considerable variation in reported costs across the country. Mean annual costs calculated for firms who returned a survey from Washington, $4,600, were close to the lowest FDA cost estimate for small firms with no GMP costs of $4,000. However, the average annual costs reported by firms in Texas, $27,240 was approximately three times higher than the FDA estimate of $9,900 for small firms with GMP costs. Based on this survey data, it would appear that FDA estimates of annual HACCP costs were consistent with survey results for the smallest firms, but costs were considerably higher for larger firms and for firms in many regions of the United States with higher operating costs.

Effort Devoted to Routine HACCP Activities

To determine the amount of time devoted to the routine activities associated with the HACCP system, survey respondents were asked to report **how much time is spent per week meeting each of the routine requirements of the seafood HACCP regulation from the list provided.** A list of eight activities associated with HACCP, sanitation monitoring, or record keeping was provided, and respondents were given an opportunity to identify other activities. The original survey questionnaire distributed to seafood firms in New York, Rhode Island and Connecticut in 1998 did not ask respondents to assign a specific time to these activities, but to choose the two activities that take up the majority of time. As a result, the data shown in **Table 38** only

represents the responses received from the national survey conducted in 1999, and does not include responses from New York, Connecticut and Rhode Island.

Table 38. Time spent on routine requirements of the seafood HACCP regulation.

Monitoring Records	Mean hours/week	Median hours/week	Range	Number of Responses
Product Handling Procedures	**7.0**	**2.0**	**0-450**	**218**
Sanitation Procedures	**6.6**	**2.0**	**0-300**	**359**
Monitoring Procedures	**5.1**	**1.0**	**0-400**	**348**
Monitoring Records	**4.5**	**2.0**	**0-300**	**404**
Sanitation Records	**3.0**	**1.0**	**0-100**	**389**
Verification Procedures	**2.8**	**1.0**	**0-60**	**329**
Weekly Record Review	**2.0**	**1.0**	**0-40**	**356**
Corrective Action Reports	**1.4**	**1.0**	**0-40**	**265**
Other	**2.8**	**1.0**	**0-20**	**16**

The data in **Table 38** shows that the seafood industry estimates that the largest portion of time spent on routine HACCP requirements is devoted to procedures rather than records. HACCP based systems are designed to ensure that food processors develop and utilize procedures that prevent potential food safety hazards from occurring at critical points in the operation. The responses that were received in this national survey indicate that the seafood industry has properly integrated the HACCP concept into their operations and is appropriately focusing the most attention on product handling procedures that are designed to ensure product safety. The industry has also focused an almost equal amount of time to sanitation procedures that ensure that the processing or product handling environment is clean and sanitary. The industry is also devoting considerable time to monitoring procedures to ensure that food safety hazards are under control at critical points in their operation. These are significant accomplishments for the seafood industry. Evaluations of industry practices prior to the implementation of HACCP showed that many firms were not paying enough attention to sanitation and were not monitoring critical steps in their operation frequently enough. These survey results provide compelling evidence that the industry's practices have changed and that control is improving.

These survey responses also show that considerable time is being devoted to the record keeping requirements of the FDA seafood HACCP regulation. The largest amount of time devoted to records is for monitoring records required by the firm's HACCP plan. For most firms these are the most important records because they demonstrate that critical limits have been met and food safety hazards have been prevented, minimized or controlled. This data also demonstrates that seafood firms have understood the HACCP concept and have appropriately incorporated it into their operation. It is interesting to note that the mean amount of time spent on monitoring procedures is almost equal to the amount of time spent on monitoring records. Sanitation records required by the FDA seafood HACCP regulation were reported to account for the second largest amount of time that is devoted to record keeping. Like HACCP monitoring, sanitation monitoring is a daily activity for most firms and these results are consistent with expectations for firms who are complying with the FDA seafood HACCP regulation. Corrective action reports were reported as requiring the least amount of time on average. This result would be expected for firms that have an adequate HACCP plan that has been properly implemented.

Total Costs of HACCP

The costs of various parts of the HACCP implementation process and maintaining the routine requirements of the FDA seafood HACCP regulation have been estimated so far based on data provided from the survey questionnaires. HACCP plan development costs were calculated by multiplying the mean number of hours reported for plan development by the mean reported hourly wage of plan developers. Training costs were calculated by multiplying 24 hours (three-day Alliance course at eight hours per day) by the reported mean hourly wage of plan developers and adding a common registration fee of $100. The mean of the dollar amount of money invested in equipment to meet the HACCP and sanitation requirements of the FDA seafood HACCP regulation was calculated directly from survey responses. The cost of the routine requirements of the FDA HACCP regulation was calculated by multiplying the mean number of hours per week devoted to these requirements reported by survey respondents by 52 (number of weeks per year) and then multiplying these annual hours by the reported mean hourly wage for HACCP plan developers. Total cost calculated in this manner for HACCP implementation and meeting the routine requirements of the HACCP and sanitation components of the regulation for one year are summarized in **Tables 39 through 41**.

The overall mean cost of HACCP plan development and implementation for all survey respondents **(Table 39)** was $27,172. This mean cost includes $1,338 for plan development plus $567 for training plus $15,077 invested in HACCP equipment plus $10,190 invested in sanitation requirements. The average annual cost of meeting the routine requirements of the regulation was $14,174. The total national average industry cost for implementing HACCP and meeting the requirements of the regulation for one year was estimated to be $41,346. The largest portion of this cost was the investments made in equipment, materials or services to enable seafood firms to meet the HACCP and sanitation requirements of the regulation. The lowest cost item was training.

Table 39. Total average costs of implementing the FDA HACCP regulation and meeting the regulation requirements for one year.

HACCP Plan Development	**$ 1,338**
HACCP Training	**$ 567**
Equipment Investment for HACCP Requirements	**$15,077**
Investment for Sanitation Requirements	**$10,190**
Annual Cost of Routine Requirements of HACCP Regulation	**$14,174**
Total Cost	**$41,346**

Table 40 compares the total mean costs of HACCP implementation and meeting the routine requirements of the regulation by company size expressed in terms of average annual sales. This

data shows that total costs increase with company size. The smallest firms had a total cost of $17,495, which increased to a total cost of $93,430 for the largest firms. Total cost for the largest firms was approximately five times greater than the cost for the smallest firms. However, if we compare the cost burden expressed as total cost as a percentage of average annual sales, the total cost for the smallest firms was approximately 3.5 percent of annual sales while the total cost for the two sales categories that represented the largest firms was approximately 0.5 percent of annual sales. These estimates indicate that the total cost burden for the smallest firms was at least seven times greater than for the largest firms. This relative cost differential could have a significant impact on small firms who may have been operating on a narrow profit margin prior to the implementation of the FDA seafood HACCP regulation. Since the overall seafood industry is made up of a large number of small firms the impact on the overall industry could be significant.

Table 40. Total average costs of implementing the FDA HACCP regulation and meeting the regulation requirements for one year by company average annual sales.

Average Annual Sales	HACCP Plan Development	HACCP Training	Investment for HACCP Requirements	Investment for Sanitation Requirements	Annual Cost of Routine Requirements	Total Cost
$500,000 or less	**$ 516**	**$547**	**$ 4,847**	**$ 3,650**	**$ 7,935**	**$17,495**
$500K-$1 Million	**$ 930**	**$481**	**$ 7,590**	**$ 7,754**	**$ 9,738**	**$26,493**
$1 to $3 Million	**$1,042**	**$493**	**$12,012**	**$ 7,852**	**$ 9,886**	**$31,285**
$3 to $5 Million	**$1,333**	**$527**	**$12,250**	**$10,634**	**$13,236**	**$37,980**
$5 to $10 Million	**$1,832**	**$561**	**$35,562**	**$26,690**	**$16,791**	**$81,436**
$10 - $20 Million	**$3,347**	**$588**	**$21,395**	**$16,805**	**$18,174**	**$60,309**
> $20 Million	**$3,313**	**$847**	**$22,783**	**$14,346**	**$52,141**	**$93,430**

Table 41 compares the calculated overall mean costs of HACCP implementation and meeting the routine requirements of the seafood HACCP regulation by state. The highest overall cost was reported by the seafood firms from Texas who responded to this survey questionnaire and the lowest costs were reported by the firms that responded from North Carolina. States that reported the highest overall costs like Texas, California, New Jersey and New York were among the states that had the greatest number of large firms who responded to this survey questionnaire. The data gathered in this survey clearly shows that costs were higher for the largest firms and higher costs for those states with more large firms would be expected. There was considerable variation in total costs with the estimate for Texas being approximately six times higher than that reported for North Carolina. There also appeared to be regional differences in total cost with the highest costs reported in the Northeastern U.S. and California and the lowest costs in the Southeastern states and the Pacific Northwest. This trend is consistent with general regional costs of labor and other business related expenses in these regions of the United States.

Table 41. Total average costs of implementing the FDA HACCP regulation and meeting the regulation requirements for one year by state.

State	HACCP Plan Development	HACCP Training	Investment for HACCP Requirements	Investment for Sanitation Requirements	Annual Cost of Routine Requirements	Total Cost
Texas	$1,620	$460	$22,756	$13,773	$27,240	$65,849
California	$2,096	$622	$28,498	$18,543	$14,377	$64,136
New Jersey	$1,579	$562	$11,110	$23,498	$25,799	$62,548
New York	$2,079	$921	$28,167	$ 8,697	$15,294	$55,158
Maine	$ 603	$562	$13,726	$ 9,816	$13,013	$37,720
Florida	$ 724	$433	$ 9,619	$ 9,978	$16,179	$36,933
Massachusetts	$ 815	$507	$13,113	$ 9,700	$11,716	$35,851
Louisiana	$1,103	$480	$14,277	$ 3,946	$ 9,960	$29,766
Connecticut	$ 988	$850	$ 7,118	$ 5,303	$14,472	$28,731
Maryland	$ 399	$454	$ 4,970	$ 6,987	$ 9,216	$22,026
Alaska	$1,505	$538	$ 2,255	$ 2,467	$12,059	$18,824
Washington	$1,315	$443	$ 3,898	$ 1,977	$ 4,614	$12,247
North Carolina	$ 499	$386	$ 2,214	$ 629	$ 6,570	$10,298

Total Costs Compared to FDA Estimates

FDA provided cost estimates of HACCP in the Preamble to the FDA Seafood HACCP regulation (*Federal Register, Vol.60, No.242, 12/18/95).* The cost analysis presented two scenarios: one for a small plant with no GMP costs and the other for a small plant with GMP costs included. Estimates were made for the first year (developing and implementing a plan) and for year 2 (operating the HACCP system). For small plants with no GMP costs, FDA estimated that Year 1 costs would be $5,600 and Year 2 costs would be $4,000. For small plants that needed GMP improvements, Year 1 costs were estimated to be $12,400 and Year 2 costs $9,900. In addition, based on an analysis of the few other cost estimates that were available, information from three independent sources suggested that at least for small businesses annual HACCP costs are within a range of $3,000 to $6,000 per plant if sanitation costs are not included.

If these estimates are compared to the cost estimates derived from the data collected in this survey, it appears that original FDA estimates for small plants were similar to those reported for the smallest operations with annual sales less than $500,000. Costs reported in **Table 40** for firms with less than $500,000 in sales were $516 for HACCP plan development, $547 for training, and $7,935 in annual costs for routine HACCP requirements for a total of $8,998. This cost is 1.6 times higher than the FDA estimate of first year costs for small plants without GMP costs of $5,600. What is missing from FDA's estimate is the mean expenditure of $4,847 reported being invested by these firms in equipment to meet the HACCP requirements. If we add this expenditure the total Year 1 cost reported in this survey was $8,998 + $4,847 for a total of $13,845. This total cost figure, which does not include sanitation costs, is approximately 2.5 times higher than the FDA cost estimate for firms with no GMP costs. If we include the sanitation costs reported in this survey of $3,650 for the smallest firms, the total Year 1 cost

estimated from the survey data was $17,495. This total cost was approximately 1.5 times greater than the FDA estimated cost of $12,400 for firms with GMP costs included.

Overall, results from this national HACCP implementation survey indicate that the cost of HACCP implementation and the routine requirements of HACCP for one year for the smallest seafood firms with sales less than $500,000 was 1.5 to 2.5 times greater than the costs estimated by FDA in the Preamble to the Seafood HACCP regulation.

This survey data also indicates that total costs increased proportionately as the size of the firms increased as measured by average annual sales. Total costs not including sanitation investments ranged from $13,845 for the smallest firms to $79,084 for the largest firms. The total cost for the largest firms was 14 times higher than the FDA cost estimate of $5,600 for small firms with no GMP costs. If sanitation costs were included, this survey data showed that total costs ranged from $17,495 for the smallest firms to $93,430 for the largest firms. The total cost for the largest firms was 7.5 times higher for the largest firms than the FDA cost estimate of $12,400 for small firms with GMP costs.

Overall, the results from this national HACCP implementation survey indicate that the cost of HACCP implementation and the routine requirements of HACCP for one year for the largest firms with sales greater than $20 million was 7.5 to 14 times higher than the cost for small firms reported by FDA in the Preamble to the Seafood HACCP regulation.

Annual cost of routine requirements of the HACCP regulation reported in Table 40 can also be compared to FDA cost estimates for Year 2 provided in the Preamble to the Seafood HACCP regulation. For small plants with no GMP costs, FDA estimated Year 2 costs to be $4,000. For small plants with GMP costs included, FDA estimated Year 2 costs to be $9,900. It is unclear from FDA's analysis what additional GMP costs were included. Since sanitation monitoring is a required part of the regulation these costs would be expected to be included in estimates of annual costs of meeting the regulation requirements. However, annual cost of the routine requirements of the regulation for the smallest plants derived from this survey data a very close to the FDA estimate of $9,900. Estimates from this survey indicated that: firms with sales less than $500,000 had annual costs of $7,935 and firms with sales from $500,000 to $1 million reported average annual costs of $9,738. The average annual cost of the largest firms (sales > $20 million) was $52,141, approximately five times higher than FDA estimates for small firms.

Table 42. Total average HACCP costs reported for survey respondents as a percent of average annual sales.

Average Annual Sales	Cost of HACCP requirements only as % of Annual Sales	Cost of HACCP + Sanitation as % of Annual Sales
$500,000 or less	**2.8%**	**3.5%**
$500,000 to $1 Million	**1.9%**	**2.6%**
$1 to $3 Million	**0.8%**	**1.0%**
$3 to $5 Million	**0.5%**	**0.8%**
$5 to $10 Million	**0.5%**	**0.8%**
$10 to $20 Million	**0.3%**	**0.4%**
> $20 Million	**0.4%**	**0.5%**

What was not included in the FDA estimate of cost was a measure of relative cost burden in which annual costs are expressed as a percentage of average annual sales. Cost reported as a percent of average annual sales for HACCP requirements without sanitation costs and cost with sanitation costs included are reported in **Table 42**.

Total expenditures reported in this survey related to the seafood HACCP regulation were as high as 3.5 percent of total sales for the smallest firms which make up the majority of the seafood businesses in the U.S. Total expenditures for the largest firms were 0.5 percent of average annual sales. Based on this data regardless of whether or not Sanitation/GMP costs are included, the relative cost burden of the requirements of the FDA seafood HACCP regulation were at least seven times higher for the smallest firms as compared to the largest firms. As a result, the highest cost burden of this regulation was experienced by the smallest firms which also represented the largest number of seafood firms in the U.S. who had to comply with the FDA HACCP regulation. From this information it can be concluded that the FDA seafood HACCP regulation is likely to have had a significant financial impact on the majority of small seafood firms across the country as well as the seafood industry as a whole.

Industry Attitudes and Perceptions about HACCP

Most of the survey questions were designed to obtain quantitative data about the HACCP implementation process. However, this data may not be sufficient to get an overall sense of how the implementation process was perceived by the industry. For this reason, several questions designed to obtain qualitative information about the industry's attitudes, perceptions, or opinions about HACCP and the impacts that this system and the FDA regulation may have on the industry and consumers were also included in the survey.

Survey respondents were asked "**what were the major benefits of the HACCP training program and implementation of a HACCP system for you and/or your company?"** A list of eight potential benefits that might be derived from the training program or HACCP implementation were provided and respondents were asked to check all choices that applied to them. Space was also provided for respondents to identify other benefits. The 696 survey responses to this question are summarized in **Table 43**.

Table 43. Benefits of HACCP training and implementation of a HACCP system.

492 – Better understanding of the food safety hazards that could affect my products.

450 – Better understanding of prevention/control of safety hazards that affect my products.

383 – Increased overall confidence in the safety of the seafood products that I sell.

303 – Employee cooperation and understanding of food safety and quality issues improved.

272 – Overall product quality management has improved.

163 – Improved efficiency in overall operations.

107 – Fewer customer complaints or product returns.

49 – Profit margins or business opportunities have increased.

48 – Did not respond to this question.

65 – Other: The course reinforced what we already do; I was able to stay in business; a more structured way of controlling safety and sanitary conditions of our product; no major benefits seen; formalizes the things we already do; nothing has changed; confusion over what you people really want in a HACCP plan; allowed me to obtain a commercial license; I've noticed no benefits so far; absolutely not – no benefits at all just more FDA; we always handled product properly now there is more paper work; no benefits to speak of; more pressure on customers and end users to maintain quality; no benefits at all; the only changes are extra work monitoring cooler temperature and paper work; new procedures for handling FDA agents; I sleep well; it helped me to better understand FDA regulations and criteria; protects against legal repercussions; no benefits we always strive for top quality; are you crazy – it costs business to do HACCP; we see no need for government interference in our business; some customer confidence and assurance increased; sanitation has improved; not enough control on imports; keeping these records accurately could result in a legal nightmare should your records be subpoenaed during a lawsuit; I can see absolutely nothing good about HACCP; no major benefits we had no problems before; we have not benefited financially – this has added to our cost; I have never had any complaints from any of my products, no major improvements; we had no problems before or now; one person operation that has been driven out of business because too much money has to be spent; satisfy customers on compliance issues; consumer confidence increased; there were no benefits just more paper work; none – little has changed in the way we operate we just now spend time on paper work; less negative media pertaining to the seafood industry not being federally regulated; too much paper work for a tiny processor – not needed.

These responses suggest that one of the major advantages of the adoption of the HACCP system for the seafood industry was the learning that occurred during the implementation process. The information provided to the industry through the training program and the FDA Hazards and Controls Guide played a significant role in helping a large number of seafood businesses obtain a better understanding of the potential food safety problems that could be associated with their products and how to prevent or control them. The training requirement of the FDA regulation provided a classic "teachable moment" for the seafood industry. University, Sea Grant, and regulatory officials across the country were able to take advantage of that moment to help the industry more effectively understand and address product safety issues. For a smaller number of businesses, there were additional benefits associated with the HACCP implementation process that helped them more effectively control and manage their overall operation. While these are significant benefits whose overall impact may not be realized for some time, most firms did not see benefits associated with their bottom line as it relates to profit margins, business opportunities, or fewer customer complaints.

A review of the comments that were received in survey questionnaires shows that there is a considerable portion of the industry that is frustrated with the HACCP system and does not perceive any benefits to their operation. Much of the frustration relates to the record keeping or "paper work" components of the HACCP system and the FDA regulation. There is also some frustration with the idea of increased federal or FDA regulation and the potential legal ramifications of the record keeping requirements of the regulation. At least one firm indicated that it could no longer stay in business because of the cost of the regulation.

To capture industry respondents' perceptions about the disadvantages of HACCP, survey respondents were asked to identify "**the major disadvantages associated with the implementation of the HACCP system for your company."** The survey provided a list of five potential disadvantages and respondents were asked to check all of the choices that applied to them. Respondents were also given an opportunity to identify other disadvantages not included in the list. A summary of the 594 responses to this question is provided in **Table 44**.

Table 44. Major disadvantages associated with the implementation of the HACCP system.

342 – Cost of developing and implementing the HACCP plan.

262 – Cost of maintaining the HACCP system.

207 – Impacts on employees including increased wages, workload or compensation costs.

143 – Increased product prices resulting in decreased profit margins.

62 – Changes in product line resulting in loss of business opportunities.

150 – Did not respond to this question.

156 – Other: time needed to change bad habits; increased costs cause difficulty in competing with shippers like baymen who do not have to comply with HACCP; time spent at a desk; Asian consumers are confused by the application of HACCP to Asian cuisine; we are a 2 person business and can't afford to pay employees to maintain HACCP records; the time spent on noting the time and nature of each procedure is a real hassle; the paperwork; had to stop selling salmon to sushi restaurants because they wouldn't accept the product; it duplicates other records that we keep so it is somewhat obsolete; the paperwork; there were no disadvantages; owners time spent monitoring records; owner of current facility won't make improvements; time and effort spent developing something that went way beyond the needs of my business; time spent on vendor compliance for importing; increased paper work for my small company is a real problem; loss of time for work; increased paperwork; production decrease; time consuming but well worth it; it's worth fighting for no complaints; just time; excessive record keeping; trying to keep up with the regulations; disproportionate inspection enforcement; more government paper work; it serves no useful purpose; inconsistency of inspectors; time spent on HACCP plan; less competition and less complaints on prices; paper work; re-checking and writing what we have always done; we are up against competition that does not have to comply; fishermen sell directly to our customer base; cost of buying equipment; time involved in training, developing, and

implementing HACCP for a small business; too much work and added cost to add new products; we dropped our wholesale business entirely causing a 10% drop in gross revenues; product costs have gone up; time spent documenting and monitoring procedures that were already clean and safe; excessive paper work; too much paper work; dealing with the FDA – they are not nice people – they do not try to help only enforce regulations; we feel it is important and not a disadvantage; implementation standards seem to change each time an inspector comes to my facility; no major disadvantage; we do not sell to non HACCP businesses; it is hard to stay on top of everything; difficulty in attending a course – I had to wait over 1 year in my area; FDA involvement in the business; travel for training; tedious record keeping; excessive record keeping and documentation especially of repetitive procedures; interaction with regulatory agency – they were not ready and were only patrolling large plants and not the small plants; no major impact; I think that it is a government CYA program; having to maintain and keep records that are not relative or necessary to our particular part of the seafood industry; the three day class caused me to miss too much work – most people in seafood have small businesses and must be at work every day; time spent learning about what we were already doing; no regulations for fishing boats and common carriers; time away from the office to attend training; time; the regulation did not target the problem spots; inspections are excessively lengthy; too much paper work – what is the benefit of writing 200 numbers a day; 14 hours per week added to my already full week; there were no major disadvantages; just trying to understand what is needed in your paper work; loss of valuable time doing paper work; the only people happy about HACCP is the news media; time lost; too much paperwork; wasted paperwork; there are too many seafood dealers that don't need to implement HACCP; lack of common sense in inspectors; does not correct area of real concern – mishandling by end user or retailer or restaurant; I lost three days with the course and about $3,000 more regulatory burden on our business; time spent on paperwork; paper work; just further paper work burden from government with no added profits; the time it takes; unclear policies regarding the storage of seafood; increased workload for 1 man crew; we stopped selling certain items; failure to have clear requirements from FDA – their standards are based on old data; increased documentation and finding capable personnel to implement this documentation; no major disadvantages; not having the FDA, USDA, and USDC on the same page regarding HACCP requirements and CCPs; too vague – self monitoring doesn't work; too much time spent on paper work; no major disadvantages just figuring out the proper paper work; nothing is being done to stop individual fishermen from processing and selling fish without the regulations – this is unfair to our business; keeping records because the same procedure is repeated over and over – I am a small business and much of what I had to learn does not apply to me and I work alone and don't have employees to keep records; the worst offenders are not being regulated; I had to build a new building; it brought competitors up to our level of sanitation; increased demand on my time as a single person operation; time spent; time wasted on paper work means less time for cleaning; too expensive; impact on employees – changing procedures; mainly time lost on record keeping; time involved in development and maintenance; other companies or trucks are buying and selling product without HACCP and they are buying it cheaper than I can; documentation is troublesome.

The survey responses indicate that the majority of seafood businesses considered the major disadvantage of the HACCP system required by the FDA regulation to be the time and cost of developing the system. Most businesses did not keep the kind of records required for a typical HACCP plan prior to the implementation of the FDA regulation. The complexity and number of different HACCP plans needed for typical wholesale operations that may handle up to 100 different products over the course of a year made the development and implementation process

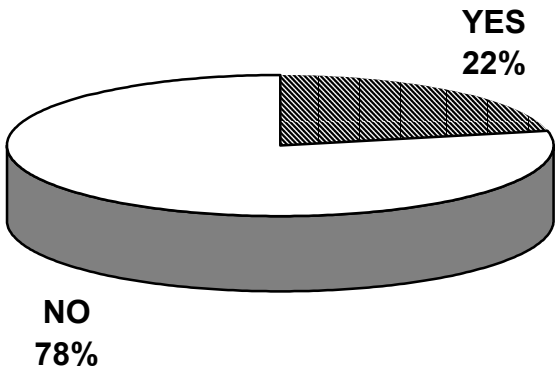
more complex and time consuming than many had originally projected. While most firms recognized the need for effective food safety controls for their products, the general feeling in the industry was that the system was more complex than was needed and the record keeping and documentation requirements were excessive. Small businesses appeared to experience the greatest impact and were more likely to report that the time and cost of HACCP plan development and implementation was the major disadvantage of this system. The comments received for this question were captured in the entirety and are quite revealing. Most firms who commented were very frustrated by the paper work or record keeping requirements. This was frequently expressed by small businesses. A number of comments also related to consistency of inspections and enforcement of the FDA regulation. Some survey respondents also reported lost business opportunities as a result of these requirements.

A number of the businesses that responded to this survey question felt that specific economic impacts related to increased employee costs, increased product prices, or lost business opportunities were the major disadvantage of the HACCP system. These economic disadvantages were more likely to be noted by small businesses. Since entire industry sectors were required to comply with the FDA regulation, the costs incurred by each individual business were also incurred by their competitors. This reduced the potential economic impact experienced by any individual business that had an existing operating system that could be adapted to HACCP. Some respondents, however, were concerned that although some of their competitors should be complying with the FDA HACCP regulation they are not and inspection efforts do not appear to be targeting or attempting to find those businesses who may not be easily identified.

Impact on Product Prices

Since cost was anticipated to be one of the major disadvantages of HACCP for many in the industry, two questions were included to determine if these costs had an impact on product prices. Survey respondents were asked "**did the average price of the products you sell increase because of the requirements of the new FDA HACCP regulation?"** The responses received from the 686 firms who answered this question are summarized in **Figure 5**.

Figure 5. Did the price of the products you sell increase because of the requirements of the HACCP regulation?

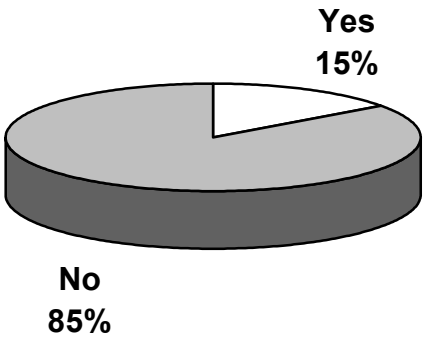


Survey responses indicated that for the majority of seafood businesses, product prices did not increase as a result of the increased costs associated with the implementation of HACCP. A number of comments were received that suggested that although prices should increase, the nature of the competition in the seafood industry and the already high consumer price of seafood make it prohibitive to try to recoup HACCP costs by raising product prices. Most respondents viewed these costs as another increase in overhead that continues to decrease their already slim profit margins. However, 150 survey respondents did indicate that prices had increased, and 101 provided an estimate of the average increase in price that they observed or experienced. The average reported price increase was $0.37 per pound with a median increase of $0.10 per pound and a range from $0.01 to $1.00 per pound.

Were New Employees Hired?

When HACCP was first introduced, many in the industry felt that they would have to hire additional employees to keep records and meet the regulation's requirements on a routine basis. A survey question asked "**did you hire any new employees to handle HACCP requirements such as record keeping or to manage or conduct sanitation tasks?"** The majority (85 percent) of survey respondents, however, reported that they did **not** hire any new employees to meet HACCP requirements. New employees were reported to have been hired by 104 survey respondents (15 percent), and 98 provided information on how many employees were hired. The calculated mean number of employees hired was 1.38 with a median of 1 new employee and a range from 1 to 4 new employees. Of the 104 respondents who reported hiring a new employee, 100 provided an estimate of their additional annual cost, which included employee salary and benefits. The mean additional annual cost for employees was $27,025 with a median of $22,000, a mode of $15,000 and a range from 0 to $125,000.

Figure 6. Did you hire any new employees to handle the HACCP or sanitation requirements of the FDA regulation?



Industry Perceptions of Related Impacts

A series of questions were included in the survey to determine the industry's attitudes about the impact of HACCP and whether they felt that the industry and consumers have benefited from the implementation of HACCP. Responses to these questions are summarized in **Figures 7, 8, and 9**.

Figure 7. Do you think that the seafood industry has benefited by implementing HACCP?

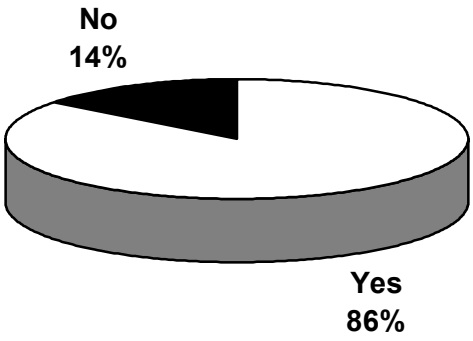
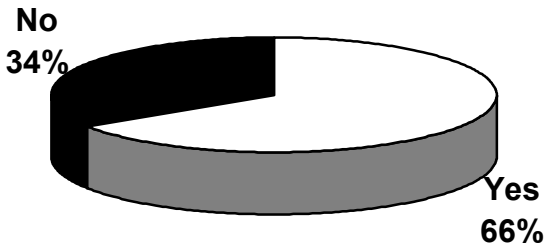


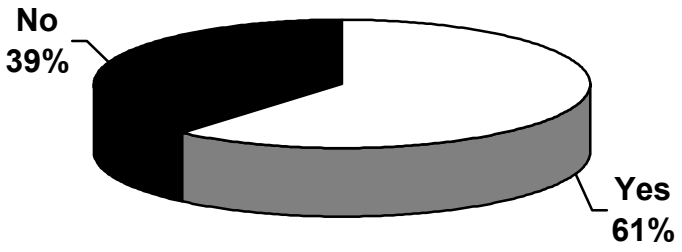
Figure 8. Over the next three years do you think that the overall benefits of implementing the HACCP system will outweigh costs for your company?



Survey responses summarized in **Figure 7** show that the majority (86 percent) of the seafood firms who responded to this survey felt that the industry has benefited from the implementation of a HACCP-based system. It is likely that this perceived benefit is directly related to earlier observations in which most respondents indicated that they now feel more confident that all of the products they sell are safer. Only two thirds of the industry respondents, however, thought that over the next three years that the overall benefits of HACCP will outweigh the costs for their company **(Figure 8)**. This perception tends to re-enforce other data gathered in this survey that shows that HACCP implementation and maintenance costs are significant and many respondents felt that the disadvantages of HACCP were equal or more significant than the benefits.

The survey question summarized in **Figure 9** was designed to evaluate whether the industry feels that consumers will benefit from this new system. Only 61 percent of the industry respondents felt that consumers would realize benefits from the new HACCP system. The goal of any food safety system including HACCP is to ensure that products are safe for the ultimate consumer of the product. Although the seafood industry has invested the time and resources necessary to understand and implement HACCP, a significant portion of the industry does not appear to believe that consumers will realize any significant benefits from the implementation of a HACCP based food safety control system for seafood products.

Figure 9. Do you think that consumers will realize benefits from the new HACCP requirements?



Industry Comments on the Most Significant Changes Observed

A number of survey questionnaires returned from the 1999 national survey contained a variety of comments that were not specifically related to any question. In the 1998 survey which was distributed to seafood firms in New York, Connecticut and Rhode Island, two questions were included in the survey to provide respondents with an opportunity to provide comments and to identify **"the most significant change in industry practices or attitudes that you have observed as a result of the HACCP training program and as result of the implementation of the new FDA seafood HACCP regulation."** All of the comments that were received in the national survey and in response to the two questions in the 1998 survey are summarized below. For the most part, these comments speak for themselves, and in all cases they provide valuable insight into areas of accomplishment as well as areas that may pose potential problems. Overall, it is clear that significant improvements have occurred in the industry's knowledge about food safety controls and sanitation and changes have occurred that have led to improvements in product safety, quality and sanitation. It is also clear that there is a significant sense of industry frustration over the paper work associated with the FDA regulation and enforcement of the HACCP regulation.

- No change in industry practices.
- Cleaner facilities and fish is being iced better.
- Lots of talk about it. Complaints about paper work. Lost product due to time & temperature.
- Increased awareness.
- Upset because people with just a van are still in business or working under someone else's roof.
- Better treatment and prevention of disease, control of parasites. The most significant hazard is pathogens from harvest area and this change is the most significant I've observed.
- The smaller distributors have gone more underground to avoid having to comply.
- A new sense of responsibility to the public in ensuring that consumption of any seafood is safe.
- Temperature control of products.
- None

- Time-temperature control is tightening up. A more accurate and realistic knowledge of the detrimental effects of poor seafood handling in the post harvest phase.
- Hazards in fish came through. Product better iced.
- Improved temperature control.
- Do not know.
- More paperwork.
- None
- Keep everyone conscious of hazards.
- Temperature monitoring.
- The attitudes toward HACCP are very mixed from proactive to totally unnecessary.
- Temperature control and cross contamination safeguards.
- Instead of being afraid of the inspectors there are more companies complying with the regulations. As a result more people are on the same page.
- Safer seafood products.
- Structured and organized way of making sure all safety regulations are met.
- Temperature is discussed more often than it was before.
- Better handling and storage.
- Better attitude among manufacturers.
- Care of seafood is better.
- More people care about temperature of fresh seafood so they use more ice.
- More confidence in the product.
- More of the companies need to learn about HACCP and keeping the product always fresh until they are delivered to the markets.
- Workers are more inclined to keep product from reaching a critical point.
- Our customers started to ask for a letter of guarantee that our company imported products in compliance with the HACCP regulation.
- Everyone in the fish market is temperature conscious.
- Generally an increased awareness of food safety and plant sanitation and its impact on quality.
- Most companies will comply with the regulation until it is inconvenient for them.
- Not noticeable.
- None to date.
- Better records.
- More paper work to do.
- Better compliance and awareness in industry practices.
- More paper work.
- Better shellfish handling.
- Better quality.
- The most significant change I have noticed is sanitation.
- More understanding of the FDA requirement.
- Fulton Fish Market seems to be cleaned up a lot compared to last year. Hurray!
- All positive.
- Better quality in general. Also less resistance to refusal due to temperature and quality. Bigger gaps in available imported products – Pacific Rim.
- Cost of materials.

- More customer interest in HACCP certification of suppliers.
- Much more awareness of microbiological hazards.
- People in the business have had to hire record keeping personnel and purchase new trucks and coolers. Prices of products we sell have risen.
- Standard to improving according to the new regulations for safety.
- Company's organizational skills in seeing that their seafood products are safe to the public have risen dramatically as well as their knowledge to follow through on these practices. Sanitation is much more closely monitored.
- As an importer I notice that some kinds of fish are getting harder to import simply because the processors in foreign countries are having difficulty getting HACCP certificates.
- Newer and better equipment (trucks), upgrade in facilities – more paper work.
- Cleaner facilities keep fish better.
- Manage the paperwork and anticipate that FDA will look at what they feel is important.
- Concern on sanitation and storage only.
- A heightened awareness of the hazards related to seafood.
- Better sanitation.
- Keep the cooler clean and sanitation.
- Increased awareness and accountability.
- Wholesalers are more aware of hazardous fish.
- Improved temperature control.
- Do not know.
- Keeping records.
- I feel that policing the industry will keep all the bad blood out.
- Several participants were positive and received a greater understanding of the requirements of HACCP while others were completely overwhelmed.
- Better handling of product and much better temperature controls.
- Awareness
- I find that more people in the industry talk about HACCP and comply.
- A cleaner work environment.
- Potential health risks related to seafood production have been learned resulting in more time and attention spent on ensuring safety precautions.
- Some have at least become aware that they have a responsibility for health.
- The distribution industry is starting to take notice of the importance of HACCP.
- More diligent record keeping.
- Better temperature control in shipping.
- Awareness of food hazards among business consumers.
- Icing and temperature control.
- Improved in so many ways at the Fulton Fish Market.
- The program has generated more paper work, more administration, more cost, with little benefit to the already conscientious purveyor.
- Better understanding of hazards and how to prevent them in my operation.
- Change in attitude, more concern over safe handling. More aware of safety issues and prevention.
- Workers are more likely to ice product.

- Our US customers favor "green ticket" packers more than before, and price difference seems to be clearer now.
- Everyone at the Fish Market is temperature conscious.
- Acute awareness of source, harvest dates, quality of fish and shellfish purchased.
- Generally an increased awareness of food safety and plant sanitation and its impact on quality.
- Industry is being more and more careful with seafood.
- Focus on paper work.
- Shellfish handling
- Quality
- Everyone is more aware of the product being purchased.
- Give out the knowledge of how to handle seafood.
- Customers are concerned – our documentation makes them happy.
- Better knowledge of risk and potential hazards.
- Very positive.
- Cleaner product – everyone now talks the same talk.
- Everyone is aware that quality risks endanger his own job.
- Heavy record keeping on paper.
- Documentation
- People have tried to update their refrigeration. Some have gone out of business due to the cost of meeting the requirements.
- Cleanliness
- Cleaner products and cleaner facilities.
- Companies are much more conscious of temperature control of HACCP regulated fish.
- Small companies with minimum employees have a tough time with the paper work.
- Public and industry awareness.
- Not accepted because they will have to comply with the regulation.
- Distributors used to treat ice as if they were diamonds. Now they are more generous in icing product.
- Industry is being more careful with the seafood.
- Better records.
- Everything we buy seems to look better and more care is taken when they pack and ship it.
- Companies are more aware of food safety for the public.
- Inspectors are more interested in observing records.
- Increased awareness of seafood hazards.
- I think the industry has to move towards a global economy (standardized).
- Worrying people too much.
- General knowledge increased.
- Tighter processing procedure resulting in safer manufacturing practices.
- Sanitation and monitoring procedures have improved.
- The industry will and has strived to put a safer product out to the public.
- Better sanitation and temperature control by suppliers.
- I haven't been in business this year so I haven't noticed much other than people switching to strictly retail sales.

- Healthier attitude towards the product being sold, but there are those who are not following the HACCP program. These are the ones that should not be in business.
- Careful handling of products.
- Tighter processing procedures resulting in safer manufacturing practices.
- Employee monitoring and compliance has improved.
- Greater overall awareness of how one person's handling of the product can affect another person's handling and sale of that product.
- Refrigeration and sanitary transport.
- People are being a lot more careful.
- The dollar investment to meet new federal certificate requirements.
- Employee awareness of CCPs.
- Nothing significant.
- Quality of product has improved.
- Industry has become more aware of paying to provide quality product.
- Bootleggers are being eliminated.
- Better sanitary practice by employees and a cleaner work place.
- Better product. We only buy from HACCP companies.
- The good companies haven't changed much. The poor companies upgrade, quit, or deceive.
- People are much more aware of the contamination problems with our products.
- Accountability! From where and at what date and temperature.
- Just meeting paperwork and minimum requirement.
- Big companies are trying to capitalize and possibly consumers will be more informed.
- Better quality control monitoring procedures.
- Individuals are more aware but overall quality is no better. It just added a new layer of paper work.
- Better awareness of the need for sanitation.
- Quality consciousness.
- Attention to seafood health via monitoring and criteria.
- Attitudes – more of a general distrust of the red tape of the FDA bureaucracy.
- More concern over cleanliness of product and materials used.
- Overall, more awareness of not making anyone (customer) sick from bad seafood.
- Some of the poorer companies have had to clean up their act or be forced out of business.
- Less of the old way of doing things.
- None. Most of the regulation was already in compliance but it wasn't documented.
- More accurate record keeping.
- Better sanitary practice by employers.
- Conditions that maintain product quality.
- More aware of food safety.
- More documentation of what is being done.
- Confusion over what you really want in a HACCP plan.
- Prices have gone up. Product availability has gone down.
- Too many forms to fill out.
- Product handling and sanitation.
- Awareness
- Be more responsible and sell a better product.

- Refrigerated trucks.
- Warning label on shellfish tags has a negative effect.
- Have not made any observation.
- More ice and better storage, especially at Fulton Fish Market.
- Higher standards for seafood being delivered.
- More false dates on shellfish receiving.
- More disgust with the government, not because of the HACCP plan – we all realize that it will help our product even if the public never finds out that it was implemented, but because you require our participation but there was no clear, concise explanation of what you wanted from each company. Just a huge, confusing morass of information and generalized requirements for a diverse industry, but no attempt to structure the training for each individual type of company.
- Frustration, but in the long run everyone will benefit, we hope.
- Spend more time doing paper work.
- Cleaner
- To sell the finest and safest product.
- Have not observed any change.
- We spent all of the time in class and at least one company I am familiar with should have been able to write a HACCP plan without repeated rejections.

SEAFOOD HACCP IMPLEMENTATION SURVEY

NOVEMBER 1999

HACCP Training

1). Do you think that your company would have been able to develop a HACCP plan to meet the requirements of the FDA regulation if you had not attended the training course?
____ Yes ____No

2). Did the HACCP training course provide you with a basic understanding of HACCP principles? ____ Yes ____ No

3. By the end of the course, did you understand what you needed to do to comply with the new FDA Seafood HACCP regulation? _____ Yes _____ No

4). What was the most important thing that you learned in the HACCP course?
_____ What food safety hazards could be associated with your products.
_____ How to prevent or control the food safety hazards associated with your products.
_____ How to develop an appropriate HACCP plan for your operation.
_____ The requirements of the new FDA seafood HACCP regulation.
_____ Basic sanitation requirements and Good Manufacturing Practices.
_____ Other (Please explain) _____

5). Do you think the seafood industry has benefited from HACCP training? ___ Yes ____No

6). Do you think that additional training courses on specific food safety or HACCP related topics should be developed for the seafood industry? ____ Yes ____ No

If yes, Please indicate what courses you or your employees would attend or what courses you'd encourage your customers (firms not covered by the FDA regulation) to attend.
____ Developing a Sanitation Standard Operating Procedure with records.
____ Basic employee sanitation training.
____ Yearly update session covering changes in FDA guidance on hazards and controls.
____ Importation requirements of the FDA Seafood HACCP regulation.
____ Short (1 day or less) training sessions on specific seafood safety hazards.
Please indicate what topics would be of most interest to you:
____ Handling & regulations for bivalve molluscs (e.g. clam, oysters)
____ Preventing scombroid (histamine) poisoning
____ Controlling microbiological hazards in cooked or ready to eat products.
____ Process controls for smoked and/or vacuum-packed fish
____ Procedures for controlling hazards on fishing vessels.
____ Other topics _____

7. Would you use training courses on any of these topics for yourself or for your employees if they become available over the Internet? ____Yes ____No

HACCP Plan Development & Implementation

8). Did you or one or more of the company's employees write your firm's HACCP Plan?
_____ Yes _____No

9). If Yes, Please estimate how much time your company spent developing and writing your HACCP plan? (Consider the number of people who were involved in developing the plan and the amount of time that each of them spent on that project).
_____ Total number of hours your firm spent developing & writing the HACCP plan.
_____ Average hourly wage of the employees involved in developing your HACCP Plan.

10). Please estimate the approximate amount of the time that was spent developing the following parts of your HACCP system:
_____ **hours spent** Conducting a Hazard Analysis **for your operation**
_____ **hours spent** Developing and Writing **your company's** HACCP Plan
_____ **hours spent** Developing **Monitoring, Corrective Action & Verification** Record Forms
_____ **hours spent** Developing Sanitation Procedures and Records

11). What changes have you made in your operation and plant facilities to meet the HACCP requirements of the FDA regulation? Check all that apply.

____ Changed the way that you evaluate some or all products at receiving.
____ Changed how you store products and monitor storage conditions.
____ Verified one or more processing procedures to control food safety hazards.
____ Changed packing or shipping techniques for higher risk products.
____ Use more ice during storage, display and shipping to control product temperature.
____ Use thermometers or other monitoring devices more frequently.
____ Use test kits or send samples out for laboratory analysis.
____ Other (Please explain)_____

12). Please estimate how much money you have invested in equipment to meet the HACCP requirements of the FDA seafood regulation **(see Question 14 to report sanitation costs).**
$_____

13). What equipment did you purchase, upgrade, or modify? (Check all that apply)

____ Coolers	____ Display units	____ Shipping Containers
____ Ice machines	____ Thermometers	____ Other monitoring devices
____ Delivery Trucks	____ Truck reefer units	____ Product test kits
____ Laboratory Services	____ Computers or other office equipment	

____ New Processing Equipment (Describe)_____
____ Other Equipment (Describe) _____

14). Please give an estimate of how much money your company has invested in new equipment or services to meet the Sanitation requirements of the GMPs and/or HACCP regulation.

$_____

15). What changes have you made in your plant facility to meet the Sanitation and Good Manufacturing Practice (GMP) requirements? (Check all that apply)

____ Purchased, modified, or upgraded physical structures (floors, walls, ceilings, drains etc)
____ Purchased or upgraded equipment such as sinks, hand wash stations etc.
____ Changed cleaning and sanitizing procedures.
____ Changed company policies regarding employee health and personal hygiene.
____ Changed or modified support services such as pest control, garbage removal etc.
____ Conducted employee sanitation training programs (formal or informal).
____ Other (Please explain) _____

16). What Sanitation equipment or services did you purchase, upgrade, or modify? (Check all that apply)

____ Hand wash stations	____ Triple/Double sink	____ Cutting tables
____ Cutting Boards	____ Knives or other utensils	____ Display units
____ New sanitizer or cleaner	____ Power washer/sanitizer	____ Hand sanitizer
____ Light fixtures	____ Employee supplies (hats, aprons, gloves etc)	
____ Floor surfaces	____ Wall or ceiling surfaces	____ Pest control

____ Other (Please describe) _____

17). Please estimate the total number of hours per week that you devote to the routine requirements of the FDA regulation including the HACCP plan and sanitation requirements.

_____

18). From the following list indicate how much time you spend **per week** meeting the routine requirements of the seafood HACCP regulation.

____ Hours spent on **Monitoring records**	____ Hours spent on **Monitoring procedures**
____ Hours spent on **Sanitation records**	____ Hours spent on **Verification procedures**
____ Hours spent on **Corrective action reports**	____ Hours spent on **Sanitation procedures**
____ Hours spent on **Weekly record review**	____ Hours spent on Product handling procedures

____ Other (Describe) _____

19). What were the **major benefits** of the HACCP training program and implementation of a HACCP system for you and/or your company? (Check all that apply)

___ Better understanding of food safety hazards that could affect my products.
___ Better understanding of prevention/control the safety hazards that affect my products.
___ Increased overall confidence in the safety of the seafood products that I sell.
___ Overall product quality management has improved.
___ Improved efficiency in overall operations.
___ Employee cooperation and understanding of food safety and quality issues has improved.
___ Profit margins or business opportunities have increased.
___ Fewer customer complaints or product returns
___ Other (Explain) _____

20). Overall, do you think that the seafood industry has benefited by implementing HACCP? ____ Yes ____ No

21). Over the next 3 years do you think the overall benefits of implementing the HACCP system will outweigh the costs for your company? ____ Yes ____No

22). Overall, do you think that consumers will realize benefits from the new HACCP requirements? ____Yes ____ No

23). What were the major disadvantages associated with the implementation of the HACCP system for your company? (Check all that apply)

___ Cost of developing and implementing the HACCP plan.
___ Cost of maintaining the HACCP system.
___ Impacts on employees including increased wages, workload or compensation costs.
___ Increased product prices resulting in decreased profit margins.
___ Changes in product line resulting in loss of business opportunities.
___ Other (Please explain)_____

24). Did the average price of the products you sell increase because of the requirements of the new FDA HACCP regulation? ____ Yes ____ No
If yes, please estimate the average price increase per pound _____

25). Did you hire any new employees to handle HACCP requirements such as record keeping or to manage or conduct sanitation tasks? ____ Yes ____ No
If yes, How many new employees did you hire? _____
What is your expected additional annual cost (salary + benefits)? _____

26). Please check one of the following items in each section that describes your business.

Business Type:	____ Wholesaler/Distributor	____ Packing Dock
	____ Custom packer	____ Processor
	____ Public Warehouse	____ Retail Warehouse
	____ Importer	____ Harvester
	____ Other (Please Describe)_____	
Number of Employees:	____ 1 to 5 ____ 6 to 10	____ 11 to 25
	____ 26 to 50 ____ 51 to 100	____ More than 100
Average annual sales:	____ $500,000 or less	____ $500,000 to 1 Million
	____ $1 to 3 Million	____ $3 to 5 Million
	____ $5 to 10 Million	____ $10 to 20 Million
	____ Greater than $20 Million	

Business Location: City _____
State _____ Country_____

Which of the following choices best describes your access to computer technology?

	At my business	At Home
I don't have access to a computer	_____	_____
I have access to a computer	_____	_____
I have access to a computer connected to the Internet	_____	_____
I have access to a computer with a CD-ROM drive	_____	_____
I have access to a computer with CD-ROM drive & Internet connection	_____	_____
I have access to a computer with a DVD/CD-ROM drive	_____	_____
I have access to a computer with DVD/CD-ROM & Internet connection	_____	_____

Thanks for completing this survey. Please return it in the enclosed postage paid envelope.