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An evaluation of the perceived obstacles for policy officials regulating the post harvest treatment of raw oysters to control the human health *Vibrio vulnificus* problem

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AN EVALUATION OF THE PERCEIVED OBSTACLES FOR POLICY OFFICIALS REGULATING
THE POST HARVEST TREATMENT OF RAW OYSTERS TO CONTROL THE HUMAN HEALTH
VIBRIO VULNIFICUS PROBLEM

A Thesis

Submitted to the Graduate Faculty of the
Louisiana State University and
Agricultural and Mechanical College
in partial fulfillment of the
requirements for the degree of
Master of Science
in

The Department of Environmental Sciences

by
Amy L. Oestringer
B.S., Louisiana State University, 2005
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Abstract

Vibrio vulnificus is the leading pathogen linked to seafood-associated deaths. This naturally occurring marine bacterium presents a human health risk when it is consumed in raw oysters. Hospitalization is necessary in 90 % *Vibrio vulnificus* illnesses and 40% end in death. (CDC) Several guidelines and regulations have been enacted to combat this human health issue, but have failed to reduce the steadily rising illness rate. Post-harvest processing requirements for raw oysters could be used to reduce illness rates. A survey was conducted to measure the perceived obstacles that regulators and industry representatives of the raw oyster industry face in policymaking to implement more stringent post harvest requirements. Members of the Florida, Alabama, Mississippi, Louisiana, Texas and California departments of health and fisheries were surveyed as well as restaurant owners across Louisiana. By examining the attitudes and perceptions of both of these groups of stakeholders, better methods of policy implementation can be derived. The objectives of this thesis are to determine if previous education efforts are reaching the industry representatives, to determine what the perceived obstacles to implantation of more stringent post-harvest processing standards are and to determine how perceptions among regulators and industry affiliates vary. The data showed that perceptions among these stakeholders diverged on several obstacles. Education efforts were shown to be ineffective alone. Resistance to additional regulation by the oyster industry was indicated as a major obstacle to the implementation of post harvest processing requirements. Cost to the producer was also cited as a major obstacle to these additional regulations. The information collected from this preliminary study has shown several areas where policy could be improved.

Introduction

In 1976, *Vibrio vulnificus* was first identified by the Centers for Disease Control and Prevention (CDC). It has since become the leading pathogen linked to seafood-associated deaths. These organisms are facultative anaerobic bacteria that are pathogenic to humans, causing illness and occasionally death. They are halophilic, often found in estuarine environments, and have been known to cause multiple illnesses including wound infection and infections, primary secondary septicemia and gastroenteritis. The most deadly route of infection is through consumption of foods containing the pathogens by at-risk population. (Louisiana Office of Public Health 2006)

There are twelve known species of *Vibrio* but only four are predominantly responsible for the *Vibrio* illnesses occurring today. These are *Vibrio vulnificus*, *Vibrio cholerae*, *Vibrio parahaemolyticus*, and *Vibrio alginolyticus*. *Vibrio parahaemolyticus* and *Vibrio vulnificus* are frequently the cause of most food-borne illness from the consumption of fish, shellfish and crustaceans. The symptoms often present around 24 hours after consumption. *Vibrio vulnificus* (*V. vulnificus*) presents the most serious risk, as there is no cure for primary septicemia infection resulting from the bacteria. Hospitalization is necessary in 90 % of these cases and 40% end in death. (CDC website) The number of cases in Louisiana has been steadily on the rise since the bacteria was first identified and linked to illnesses. Ninety-six percent of patients with primary septicemia had consumed raw oysters within seven days before symptoms onset when *V. vulnificus* infections in the United States were reviewed (LAOPH 2006).

Problem Statement

Current policy consists of voluntary guidelines for the safe shipping across state boundaries and suggestive measures for state regulation of their own oyster industry. The policies suggested by the Interstate Shellfish Sanitation Conference and those enacted by states rely largely on education of potential consumers. This education based approach to reduce illness rates has been to inform the public so that at risk individuals will not consume raw oysters. The difficulty with achieving success by these means is due to the fact that much of the at-risk population are not aware of their vulnerabilities. Recent more stringent regulation of the raw-oyster industry has required harvest and processing labels to accompany all raw oysters sold to consumers. The labeling requirement allows for better tracking and investigation of oysters implicated in causing illness. As a result, researchers from the CDC have determined that all oysters identified as causing illnesses were harvested from the Gulf of Mexico. In 2003 the state of California placed an emergency ban on all the oysters imported from the Gulf. In 2004 the ban became a permanent more stringent regulation that requires post-harvest processing methods to reduce *Vibrio* spp. counts in the oyster to non-detectable limits. Following the recommendations of the National Shellfish Sanitation Program, California has successfully reduced their illness rate to zero. Analysis of the actions that California took indicates that these processing requirements could be a solution for all states serving raw Gulf oysters.

This research examines the following:

1. Is health risk-related information reaching the stakeholders within the oyster-producing and sales industries?
2. What are the perceived obstacles to implementation of more stringent post-harvest processing standards among regulators and private-sector stakeholders?
3. How perceptions concerning these obstacles differ among regulators and industry affiliates?

Background

Oysters harvested from the Gulf of Mexico are known to contain the marine bacteria *V. vulnificus*, but this alone does not present a human health risk. These bacteria proliferate in warm salty conditions. Thus, when the Gulf waters are warmer the bacterial counts are higher. Eighty-nine percent of the oysters in the review were harvested when Gulf waters were warmer than 22°C (71.6°F) (LAOPH 2006) To the general oyster-consuming population the seawater temperature bears no relevance, as they may consume oysters containing large amounts of the bacteria with no adverse effects. The at-risk population, or those with compromised immune systems are the individuals that risk severe illness or death from consuming oysters with high *V. vulnificus* counts. It was suggested by Ruple & Cook (1992), that oysters should only be harvested during winter months, to avoid high *V. vulnificus* counts. As filter feeders, oysters in these waters will have higher concentrations of the bacteria in their meat than surrounding waters. The LAOPH has determined individuals with liver disease, hemochromatosis, diabetes, all cancers, leukemia, lymphoma, Hodgkin's, HIV, Long term steroid use, alcoholism, kidney disease, and the elderly to be at high risk.

Louisiana produces 40% of the oysters consumed in the United States. (Rousell, 2007) Louisiana also harvests the most oysters by weight in the nation, with annual landings in the 10-13 million pound ranges. (Wirth 2004) The LA oyster industry has contributed to the state's culture for multiple generations. The methods and techniques of these predominantly family-owned and operated businesses have been practiced for many years. Though the human health risk to consumers of raw oysters has become known and is a concern to many, there has been resistance to change in aspects of the harvesting, processing and shipping procedures. As a result of the awareness of risk, demand has decreased and the oyster industry has suffered. In order to protect this once thriving industry and to ensure demand in the future, more effective harvesting and processing policy is needed. There have been several attempts by government to implement more stringent requirements on raw oysters but these

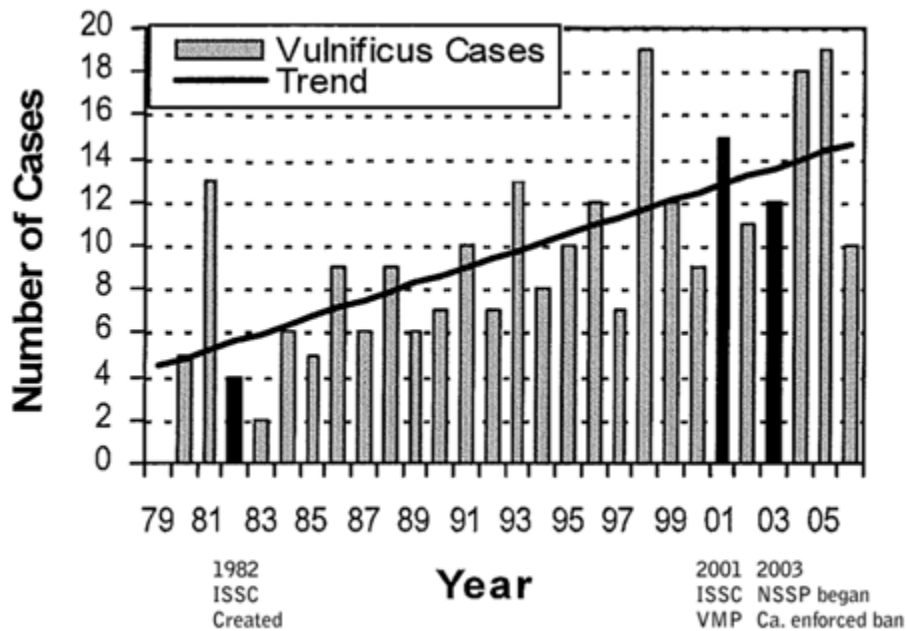
attempts have been met with strong opposition by the oyster industry. This research identifies potential obstacles to the acceptance of stricter regulation and examines how perceptions vary by regulators and industry which contribute to the implementation difficulties.

Policy Framework

The Federal Food and Drug Administration (FDA) was the first to regulate the oyster industry with no knowledge of these ubiquitous marine bacteria. Once discovered to be responsible for illness and death, *Vibrio vulnificus* attracted the attention of regulators. Officials at the FDA believed that a group of knowledgeable individuals should be organized to develop a management plan. In 1982, the FDA funded a grant which created the Interstate Shellfish Sanitation Conference (ISSC), and with their help, the FDA created the 2003 National Shellfish Sanitation Program (NSSP). This document provides suggested guidelines on which state agencies can base their policies. The ISSC has voting delegates for each state which worked with the FDA to construct the NSSP document. The 2003 NSSP was amended and is superseded by the 2005 NSSP. ISSC member states have agreed “to enforce the Model Ordinance as the requirements which are minimally necessary for the sanitary control of molluscan shellfish” (NSSP Guide for the control of molluscan shellfish 2005). The state must meet the guidelines set forth in the NSSP in order to ship the product across state lines. It may also choose to place further regulation on the industry if the actions are to further protect the public, as the document is not meant to limit state regulations.

It is pertinent that all involved parties fully understand the need for these regulations and that they understand that their participation and support is critical for success. The current solution to the human health *V. vulnificus* problem has been to educate the at risk population about the dangers of consuming raw oysters and to urge them not to do so. In 2001 the ISSC adopted the *Vibrio vulnificus* Risk Management Plan which called for efforts to educate the at-risk population. The plan included three components and several illness reduction goals to be met within seven years. Education efforts for the at-risk population, promotion of processing technology to reduce *V. vulnificus* levels, and development of regulatory controls and implementation strategies (should the goals not be met) comprise the primary components of the plan. The goals called for an illness-reduction of 40% by the

years 2005 and 2006 (average) and by 60% for years 2007 and 2008 (average) from the average illness rate for the years 1995-1999. If these goals were not met the plan then called for more stringent control, including post harvest processing.



(LADHH 2006, policy info added by Oestringer 2008)

Figure 1. Louisiana, *Vibrio vulnificus* annual cases and regulation (1979-2006)

Figure 1. displays in graphic form the steady increase in the number of illness cases caused by *V. vulnificus* from the years 1980-2006. It is important to note the regulatory changes that took place during this timeline. In 1981 the number of *vulnificus* cases was alarmingly high prompting the FDA to create the ISSC in 1982. In the years following the number of cases continues to rise. In 2001 the ISSC adopted the *Vibrio* Management Plan as the primary method for illness reduction. This plan involved education and proper labeling components, which could explain a slight decrease in cases for the following year. In 2003 California began the emergency ban on all raw gulf oysters that had not been post harvest processed. From 2003-2004 California successfully reduced their *vulnificus* illness rate by 100% and it remains this way today. The first National Shellfish Sanitation Program document, the

guide for the control of molluscan shellfish, was completed in 2003 and illness cases were expected to decline. Instead, there was a drastic increase in the number of cases in 2004 and 2005. The NSSP document was revised 2005 in an effort to more efficiently meet the goals of the reduction plans.

ISSC delegates have a unique responsibility to protect and foster the oyster industry while making decisions that protect public health. By 2002 the ISSC had developed and distributed educational materials to medical associations, and a state facilitator was designated to work with states to assist in the development of local outreach programs. They began working to provide funding for each state's *V. Vulnificus* education plan, collaborated with states to develop physician and health care provider workshops, and began the funding and development of an online physician's continuing education module.

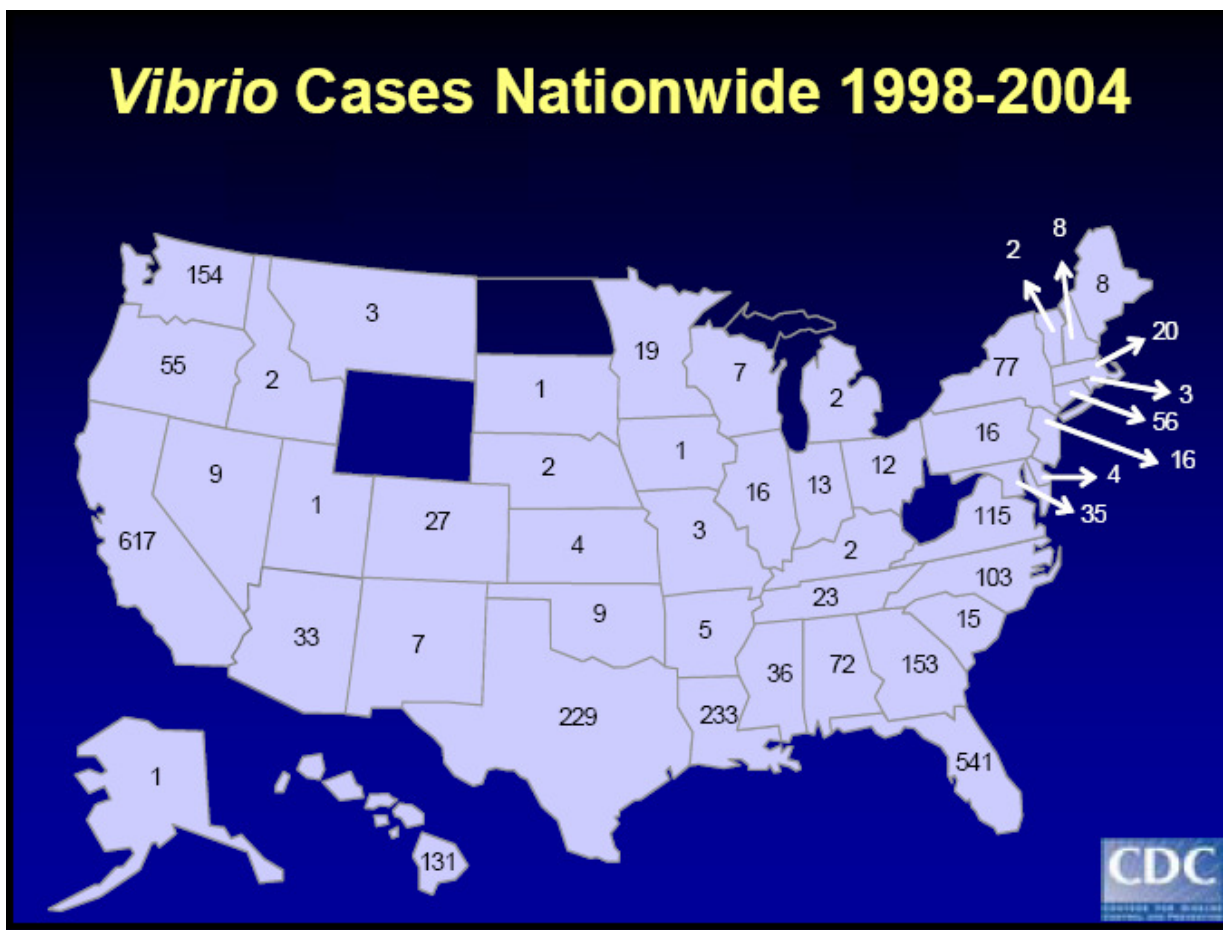


Figure 2. Cases nationwide

The previous map displays the *Vibrio* spp. illness rates nationwide. California, Texas, Florida and Louisiana had the highest numbers of incidence in the nation. CA state legislature enacted their own policy to reduce illness rates, while Gulf Coast states did not. This prompted the ISSC to begin their education efforts in LA, TX, and FL. The “*Vibrio vulnificus* Diagnosis, Prevention and Treatment” program was approved by Tulane University as satisfying the national requirements for continuing medical education for physicians in 2004. The course was offered to 15,141 licensed physicians in Texas, Florida, and Louisiana to prepare them to identify the clinical manifestation of the illness, inform them of the treatments, recognize groups at high risk and advise them to avoid raw oysters. As of February 25, 2005, participation was low, only 73 physicians having completed the course, with 42 from Florida, 26 from Texas, and 10 from Louisiana. (ISSC Final Report 2005) The ISSC defined two success criteria for the consumer information programs. The first was to increase raw oyster consumer awareness of the risk of eating raw shellfish 40% above baseline levels. The second was to increase the proportion of high risk consumers who stop eating raw oysters 15% above baseline levels. A baseline study, “Educating the at-risk consumer” was completed in 2002 to determine the effectiveness of collective *V. vulnificus* education efforts and the follow up raw oyster consumer study was completed in 2004. The findings showed the education efforts to not have been effective at significantly increasing education, nor reducing the consumption patterns of the at risk population (Raw oyster consumer survey 2004). The study also concluded that misconceptions about how to reduce one’s risk of *V. vulnificus* infection are widespread.

Though the illness and death rate has steadily risen, the data presented at the 2006 ISSC meeting showed a 43.3% reduction of illness by the core states. This data was distorted as the core states included in the average were California, Louisiana, Florida and Texas. In 2003 California banned the importation of oysters that had not been post harvest processed, reducing their illness rate by 100%. Therefore, the inclusion of California’s statistics falsely represented the actual reduction of the core

states' illness rates. This thesis analyzes the methods and regulation that have been used to date to control the *Vibrio vulnificus* human health problem at both the federal and state levels of government. The current activities enacted to educate the at-risk population as the major management plan have been reviewed, and further work must be done.

Regulatory bodies could follow the example led by California and mandate the use of post-harvest treatment for all raw oysters being sold to consumers, not just depending on voluntary means such as education. As the largest producer of oysters, the state of LA has the most to lose as well as gain with regard to demands of the oyster industry. There are three different post harvest processing plants currently operational in the state and these plants could provide increased revenue and jobs. A benefit of some processing methods is that the oyster is shucked in treatment, reducing the extensive costs of human shuckers. A cost-benefit analysis performed at a research triangle institute has shown the costs of the post-harvest processing to be offset by this, making the process beneficial. The ban that California implemented was detrimental to the Louisiana oyster industry costing an estimated 20 million in 2003. It was a precursor to the loss the industry will feel if other states implement similar regulations in the future. If all of the oyster harvested in Louisiana were processed, consumers would gain confidence and the demand would increase. The slight increase in price of the product could be passed on to the consumer and it is expected that there is a willingness to pay for a safe product.

Post Harvest Processing

There are multiple types of processing technology available throughout gulf coast states. The technology has been available for years but the demand for safe oysters is increasing now. The FDA has set a standard for all oyster processors to reduce the *Vibrio vulnificus* counts to <3MPN/g, in order to qualify to label the oyster as safely processed (NSSP 2005). There have been numerous methods explored to reduce *Vibrio vulnificus* number in raw oysters intended for the half-shell market. Commercial ionizing irradiation with Co60 reduced the numbers to meet the standards but it has not been approved as a safe method by the FDA (Kilgen 2003). Though freezing has also been shown to reduce the *Vibrio* counts; there is a significant loss of quality in the taste and texture of the meat while also reducing the shelf life. The Federal Food and Drug Administration has declared an emergency rule that oysters harvested in the summer for raw consumption must be refrigerated within five hours after harvest. This rule will go into effect June 24, 2008 and remain in effect until October 2008. This action is in response to increasing *Vibrio* illness across the nation, however this rule alone is not likely to have any effect on the increasing illness rates. A study on the effects of temperature abuse on survival of *V. vulnificus* in oysters concluded that oysters that were incubated at high temperatures (17 and 22°C) showed a large increase in bacterial counts. The data suggested that even with proper refrigeration, indigenous levels of *V. vulnificus* remain high in the oyster meat and have potential to cause infection. (Murphy & Oliver 1992) An LSU student, Kevin Melody, completed a thesis which studied the post harvest processing effects of icing and high salinity on the American oyster (*Crassostrea Virginica*). He found that icing did not work to reduce bacterial counts to non detectable limits. He was not able to complete the salinity exposure experiment but it was deemed to be unfeasible as a protist, *Perkinsus Marinus* proliferates rapidly in high salinity conditions. This protist would quickly infect and destroy the oysters, making this process ineffective. (Murray 2004)

Ultra high pressure processing has thus far proven to be the most efficient method to reduce bacterial counts while preserving the quality of the product, extending its shelf life and reducing cost. A Louisiana company, Motivaitit Inc., is using this technology by exposing oysters (50 to 60lbs) to more than 30,000 psi for two to five minutes. The result is a safer oyster with non detectable bacterial levels and no spoilage microorganisms. One of the major benefits of this processing is that the high pressure causes the oyster's adductor muscle to detach from the shell and shuck itself. (Food Engineering 1999)

Two commonly-cited criticisms of the post-harvest processing are expense and loss of quality in the product. Many industry representatives do not support regulation that would require post harvest processing of all oysters because they feel that the at-risk population is small in comparison to all other oyster consumers. This attitude does not take into consideration that individuals with diabetes and liver disease often go asymptomatic and undiagnosed until the later stages of the illness. The incidence of liver disease and diabetes in America is increasing every year, adding more people to the at risk group. (LADHH 2003) The processing methods that are available today do not cost much in terms of the overall cost of consuming oysters. It is an estimated .08 cents more per oyster to ensure that it is safe, having non-detectable amounts of bacteria. Oysters are an expensive delicacy in which middle to lower class individuals are usually not able to indulge. The oyster consuming population is of the middle to upper class socio economic status and they are able to afford a small increase in price. A study of consumer willingness to pay for depurated, or processed safe oysters, indicated that seventy percent of oyster consumers are willing to pay an average of 18 cents more per oyster. The study showed that more individuals would consume raw oysters and there would be an increase in sales if they were safe.(Degner and Petrone 1994) Some restaurants predict that sales of raw oysters will increase by 10-30 percent if they are safe. (Dunning and Adams 1995)

A restaurant owner that participated in the survey stated: “I have served Ameripure pasteurized oysters for 10 years and I am very happy with them. My customers like them and they are affordable. When Ameripure is not able to fill my order, I purchase gold band oysters from Motivati seafood but they are more expensive.” Both types of oysters mentioned are post-harvest processed oysters and this testimony states that customers have been pleased with taste and quality of the product.

It is known that warmer seawater temperatures cause an increase in the bacterial counts concentrated in the oyster meat. Temperatures globally have been steadily increasing and are expected to continue to rise. Annual mean surface water temperatures have increased by .05°C annually worldwide and will result in higher bacterial counts in Gulf of Mexico raw oysters. (Justić 1996) These changing temperatures will have no effect on the oyster industry if post harvest processing requirements are in place. There will be a reduction of the bacterial counts to non detectable limits with no regard to the initial count present at harvest. Thus revision would not need to be made continuously to the regulation to account for the changing temperatures.

Methods

Issues concerning whether the document asked the appropriate questions for the study and if the questions were clear and non biased were addressed in the following steps. Changes in the questionnaire were made based on review by graduate committee members. A developmental psychologist from the University of Lincoln Nebraska with extensive survey research experience reviewed the survey and suggested several changes. Next, a rehabilitation counseling PhD student at the University of New Orleans, with public survey research experience also suggested revisions that were made. Several lay people read the survey and commented on its clarity and ease of understanding. After the above suggestions were reviewed the revised survey was taken to the committee chair for final evaluations. It was then submitted in February 2008, to the Louisiana State University Institutional Review Board and it was approved for use in this study (Appendix A).

Data Collection

Stakeholder data can be collected in many ways, however, surveys tend to be most popular. Surveys can be administered four ways: telephone, internet, mail, or in person. The following table compares the advantages and disadvantages of different data collection procedures (Table 3.2). For this study, an anonymous internet survey was used because it provided a reasonable cost method of transporting information from respondent to researcher. Researchers often provide an incentive to increase the survey response rate, but there was no incentive offered in this study.

Survey Administration

The target population for this study is stakeholders in the raw oyster industry, including regulators and industry affiliates in the gulf coast states. California, Texas, Louisiana, Mississippi, Alabama and Florida state departments were contacted by phone to identify individuals in the office that work with the raw oyster industry. A list of these contacts was constructed including names, offices,

direct phone numbers and email addresses. These states were selected for the study because with the exception of California, they are all producers of gulf oysters and they all comprise a large portion of the consumers of raw gulf oysters. California was selected to participate as it is currently the only state in the United States to have implemented regulation requiring post harvest processing of oysters intended for the half shell market. Federal agencies that are concerned with the regulation or monitoring of the raw oyster industry such as the Centers for Disease Control and the federal Food and Drug Administration were also identified and added to the list. The Interstate Shellfish Sanitation Conference, which plays an integral part in the regulation of the industry, was added to the email list. An internet search of Louisiana restaurants that serve raw oysters, provided a list phone numbers. Restaurants in the Shreveport, Baton Rouge, New Orleans and Houma area were contacted and asked to participate. They were asked to provide an email address where the survey could be sent. These cities were chosen so that the sample would be representative of locations across Louisiana. Additionally, the only three raw oyster processing companies in Louisiana were also included in the email list.

An email message was composed, asking for participation and explaining the importance of the study as well as response information. A consent form, which further explained the details of the study, was attached to the email (Appendix B). The email asked the individual to click on a link within the text of the message that would direct them to a web survey site. At this site the survey was presented and participants were able to enter responses by clicking the appropriate bubble. After completion of the survey questions they were able to click a submit button and immediately submit the form.

Websurveyor 2.1 was the program used to administer the survey. It is an internet survey program that allows the researcher to design the survey and then publish it on the internet, where it becomes available for anyone to view. The program stores all survey participants' responses immediately, where they become available to the researcher in an excel spreadsheet. Dillman states that respondents inadequate computer skills may be a potential disadvantage in the internet survey method.(Dillman 2002) For this

reason, Websurveyor 2.1 was chosen for its ease of understanding. Survey participants were not required to have extensive computer skills to complete the survey.

In March 2008, the first email was sent to everyone on the list asking for their participation (Appendix C). Two weeks later phone calls were made to each name on the list asking them to participate if they had not already done so. Dillman has shown that security and confidentiality concerns are often a disadvantage to the internet survey method. These concerns were allayed by phone calls to ensure the participants anonymity in the survey. Three weeks following this call, the same email was sent again and follow up phone calls were made in a final effort to gain participation, as the response rate was low. Several of the restaurant managers and owners were called back up to 6 times to request their participation. One-hundred, roughly evenly divided between those with public agency and industry associations, were contacted by email asking for their participation in the survey. Twenty-eight of the completed responses were received, with 16 from industry-affiliated individuals and 12 from employees or representatives of public agencies. The relatively low response rate may be partially explained by an apparent sensitivity associated with the topic in general.

Survey Content

The survey was designed to produce information that will aid regulators and industry in accomplishing illness reduction goals that have been set previously. It aims to identify where a breakdown of communication is occurring in the industry as well as to rank obstacles that are inhibiting regulatory progress. The anonymous survey consisted of 18 questions and took an estimated 5 to 10 minutes to complete (Appendix D). Questions in the survey were used to establish a level of knowledge of the subject matter, to determine respondents' sources of information concerning reduction of risks associated with raw oyster consumption, and measure perceived obstacles to the regulation of the industry as well as post harvest processing. The survey questions were presented in a Likert-type

format to provide qualitative data. Three 4-point information rating items measured the amount of information the participant had access to regarding the risk posed by *Vibrio vulnificus* and post harvest processing methods. Another question provided the respondent a list of five sources of information on *Vibrio* illness, and asked them to choose all sources that they have used themselves. The next dimension of questions was aimed at ranking the perceived obstacles to the implementation of regulation that would require high pressure post harvest processing of raw oysters. This section consisted of six 5-point scale ranking questions that allowed the respondent to rate items as obstacles from 1 being not an obstacle to 5 being a major obstacle.

Survey Analysis

Descriptive analyses were performed on the survey results and charts generated to examine various trends in the responses. The responses collected from question 4 were cross tabulated with responses from question 17 to indicate the extent to which there is public awareness and concern for the *Vibrio vulnificus* health threat. It is expected that participants who indicated that the reduction of *Vibrio* illnesses is a major objective in their state would also rate the extent of public concern for *Vibrio* illnesses to be high as well. Responses for question 8 were tallied and placed into a table containing the percentages of regulators and industry that access each of the 5 sources of information. Data collected from the obstacle questions was combined in a table that shows how regulators and industry ranked each obstacle. Though the appropriate measure of central tendency of a data set is typically the mean, this study contained Likert scales which associated numerical values to ordinal data. This allowed for the calculation of an arithmetic mean for each item, which provided a better measure of central tendency. (Rea & Parker 1997) Cross tabulated contingency tables were created to allow for a simultaneous analysis of more than one variable for several survey questions. Several survey items questioned the amount of information available to the participant. These responses were then compared to the responses selected for certain obstacle questions.

Results and Discussion

Table 1.1 lists percentages of the various sources of information on the raw oyster industry that participants had indicated as available to them. Public health reports were most commonly cited as a source of information with internet searches as a close second. Government publications were the third most commonly cited source of information and information from the Interstate Shellfish Sanitation Conference was the least available. Differences were seen in the type of information available to regulators versus industry affiliates. Regulators received most of their information from government publications as well as from the Interstate Shellfish Sanitation Conference. Industry affiliates cited internet searches as the most available source of information with the least coming from the Interstate Shellfish Sanitation Conference.

Table 1

Sources of Information on the Raw Oyster Industry

	Total %	Regulator%	Industry%
Public Health Reports	93	100	88
Government Publications	68	90	56
Internet Searches	82	63	100
ISSC*	64	100	44
Other	32	29	25

*ISSC Interstate Shellfish Sanitation Conference

Table 2 presents a summary of the data collected from the perceived obstacle survey questions 9 through 15. Figures 3-9 show graphic depictions of this data to better show the divergence in responses between regulators and industry. Figure 3 shows that regulators indicated that insufficient scientific understanding of the risk associated with the consumption of raw oysters is not an obstacle to requirements by law for the use of high pressure post harvest processing techniques. However, industry representative responses range from somewhat of an obstacle to not an obstacle for this question. The

mean response for this question is 2.3. In Figure 4 it is shown that regulators as well as industry do not perceive uncertainty about the effectiveness of high pressure post harvest processing to be an obstacle to the implementation of such processing requirements. The mean response for the question is 2.2. Figure 5 shows that both regulators and industry believe that cost to the consumer is a major obstacle in implementing such regulation. The mean response to this question is 3.9. Figure 6 similarly shows that regulators and industry find additional cost to the producer to be somewhat of an obstacle. Several industry participants stated that the additional cost to the producer is a major obstacle. The mean response for this question is 3.4. In Figure 7 the majority of the responses fall between somewhat of an obstacle to a major obstacle for resistance to added regulation by the oyster industry. Industry representatives identified this to be a major obstacle. The mean response for this question is 4. The next figure (8) shows that industry and regulators find resistance to added regulation by the restaurant industry to be somewhat of an obstacle. The mean response to this question is 3.3. These results show resistance by the oyster industry to be more of an obstacle than resistance by the restaurant industry. These perceptions may be explained by the idea that the restaurant industry may pass the additional cost on to the consumer more easily. Figure 9 shows that both regulators and industry identified budget constraints within their agency as somewhat of an obstacle.

Table 2. Responses for perceived obstacle question 9-15
(scale ranged from 1-Not an Obstacle to 5-Major Obstacle)

		Average	STD	1	2	3	4	5
Insufficient Scientific Understanding of Risk	Reg	2		6	1	2	2	0
	Ind	2.4		6	2	6	2	1
	Total	2.3	1.3	12	3	8	4	1
Uncertainty About Effectiveness of High Pressure PHP	Reg	1.9		6	1	3	1	0
	Ind	2.4		7	3	3	2	2
	Total	2.2	1.3	13	4	6	3	2
Additional Cost to the Producer	Reg	4.5		0	0	2	2	7
	Ind	3.6		1	1	8	1	6
	Total	3.9	1.3	1	1	10	3	13
Additional Cost to the Consumer	Reg	3.5		0	1	5	4	0
	Ind	3.4		3	1	6	1	0
	Total	3.4	1.3	3	2	11	5	7
Resistance to Added Regulation by Oyster Ind.	Reg	3.8		0	0	4	5	2
	Ind	4.1		0	1	5	3	8
	Total	4	1.1	0	1	9	8	10
Resistance to Added Regulation By Restaurant Ind.	Reg	3.5		0	2	3	4	2
	Ind	3.2		3	1	7	2	4
	Total	3.3	1.3	3	3	10	6	6
Budget Constraints Within Agency	Reg	3		1	2	5	2	1
	Ind	2.9		4	1	7	2	3
	Total	3	1.3	5	3	12	4	4

N=28 (12 Regulators, 16 Industry)

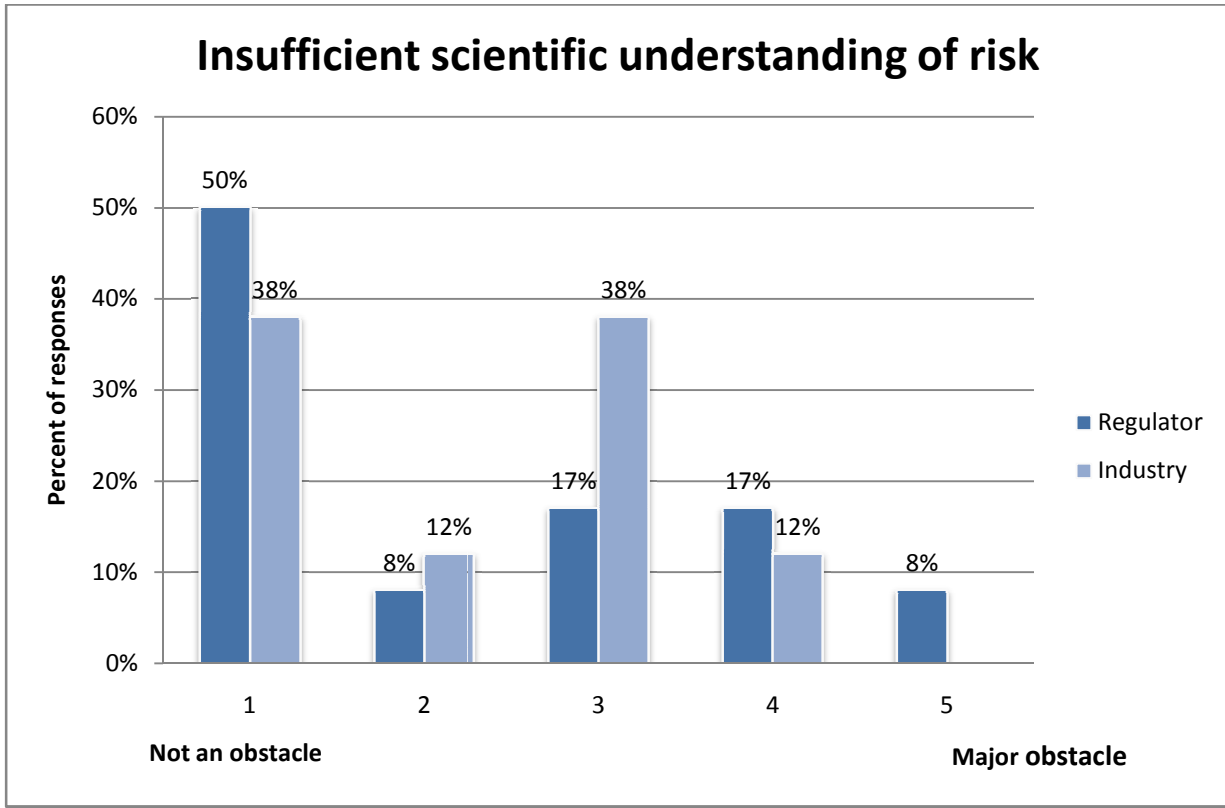


Figure 3. Insufficient scientific understanding of risk

Mean response 2.3

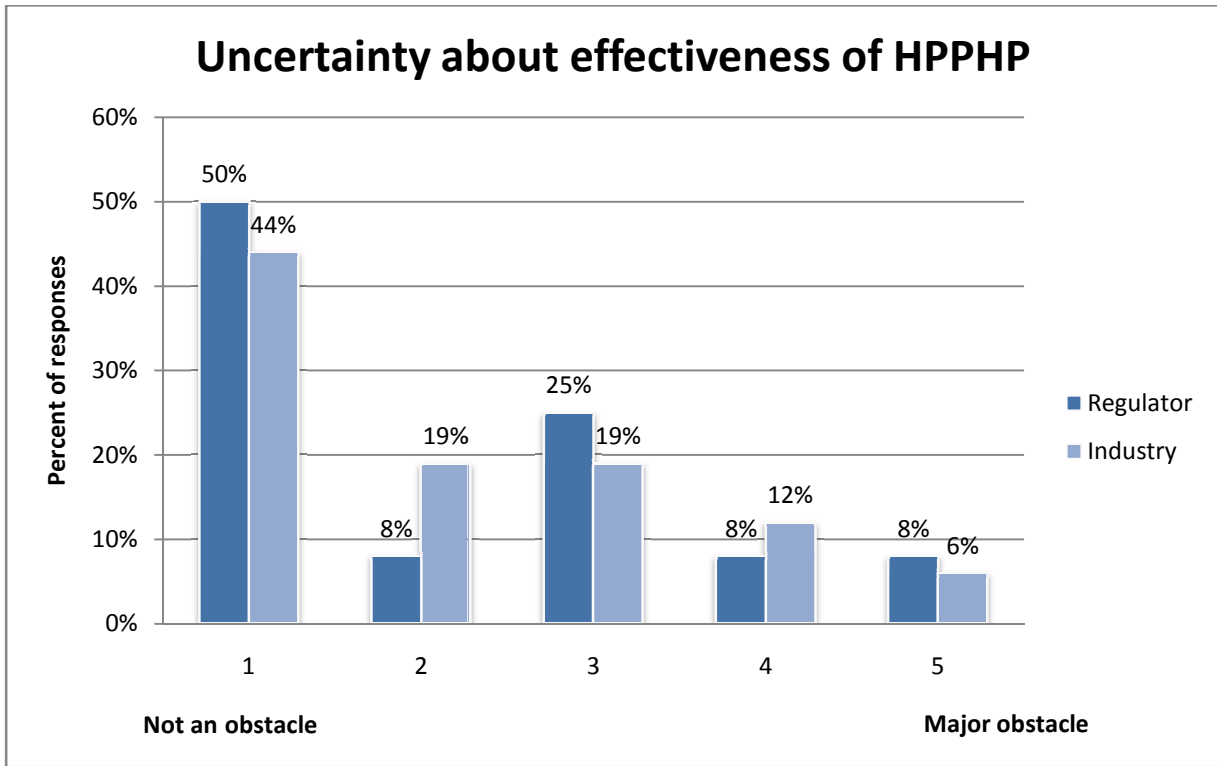


Figure 4. Uncertainty about effectiveness of HPPHP
 Mean Response 2.2

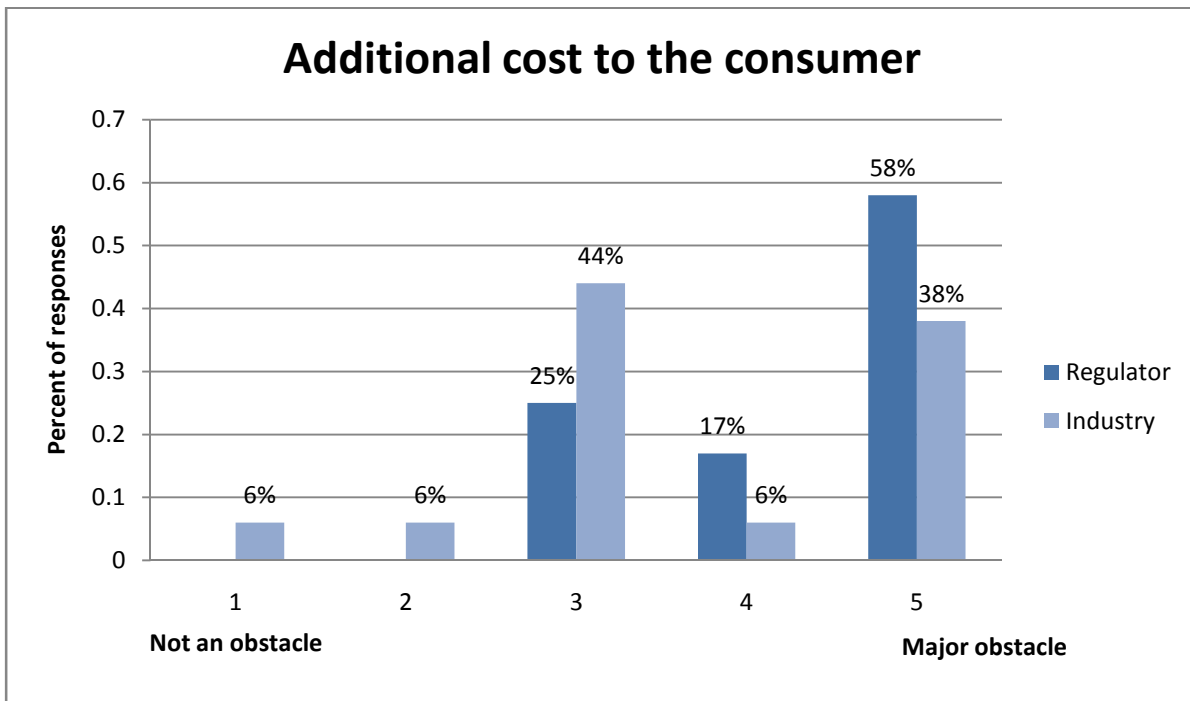


Figure 5. Additional cost to the consumer
 Mean Response 3.9

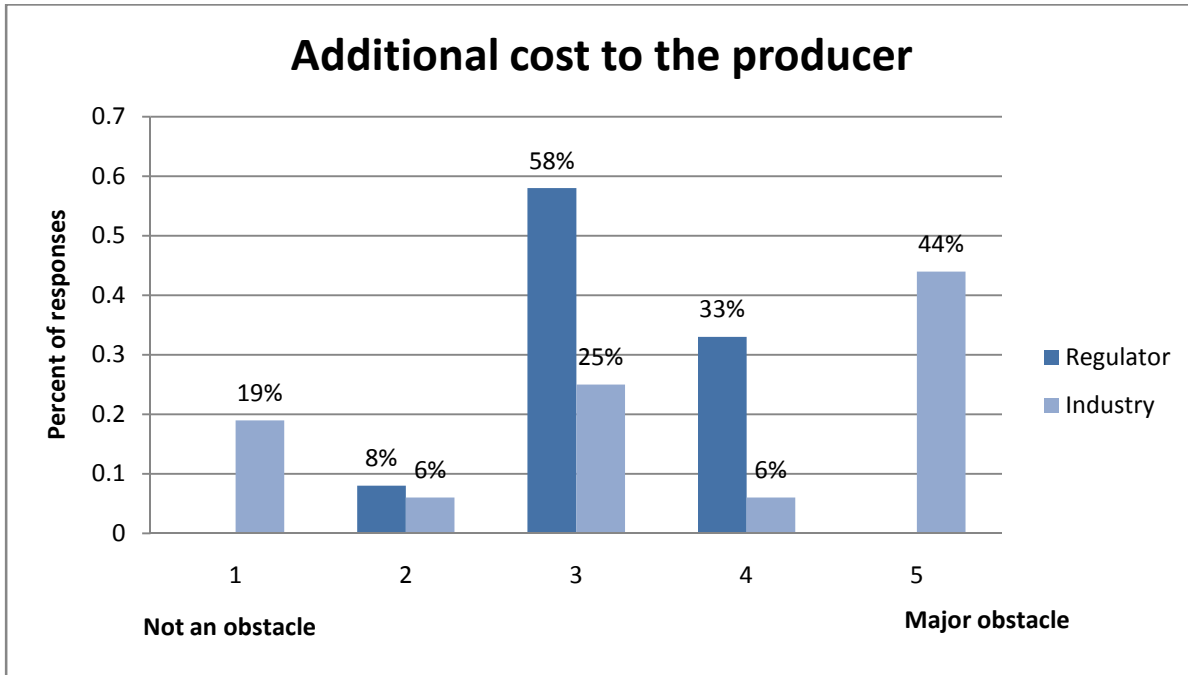


Figure 6. Additional cost to the producer
Mean Response 3.4

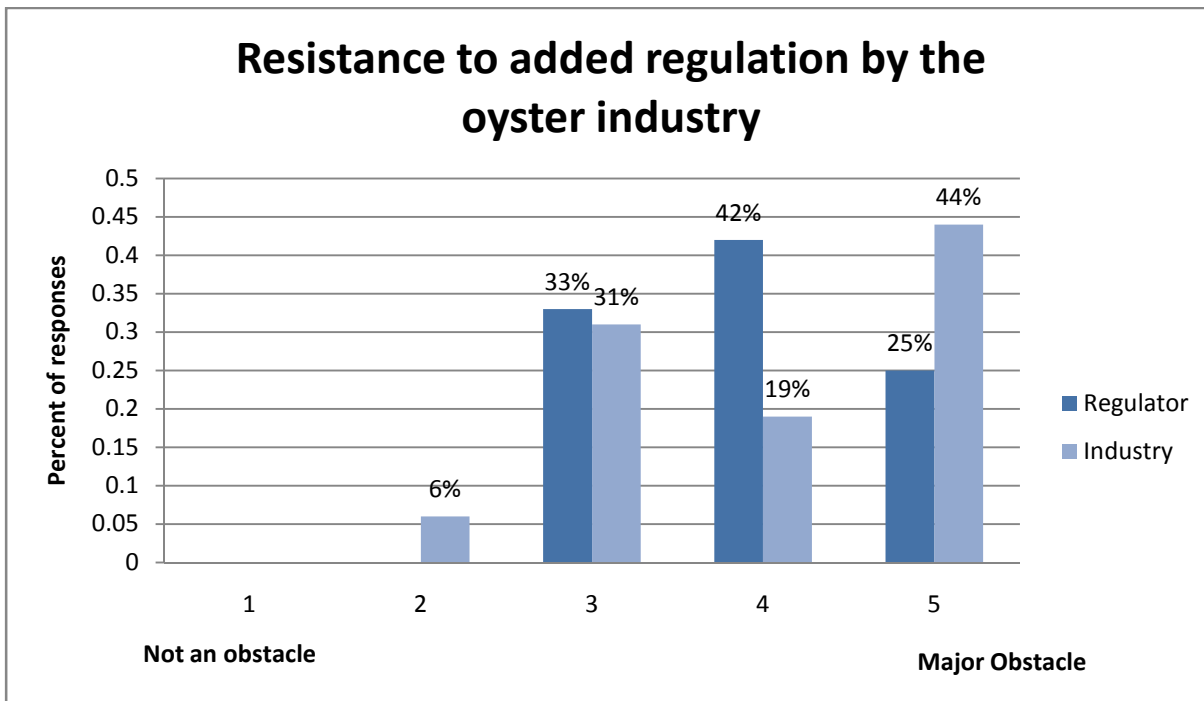


Figure 7. Resistance to added regulation by the oyster industry
Mean Response 4

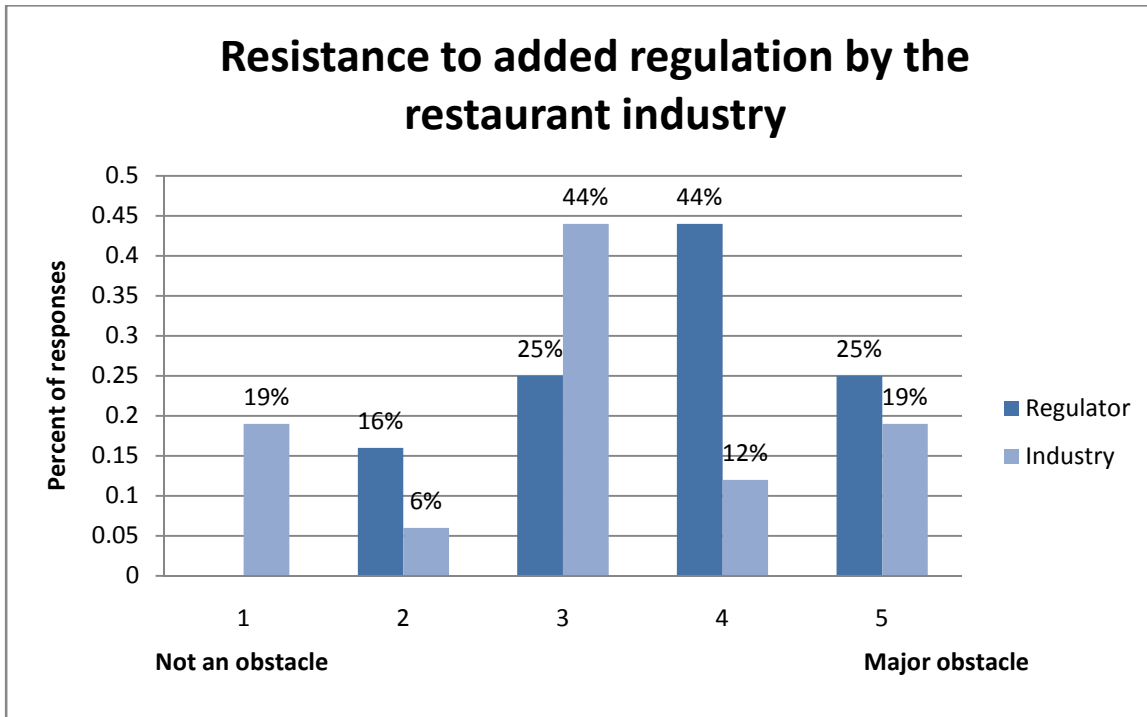


Figure 8. Resistance to added regulation by the restaurant industry
 Mean Response 3.3

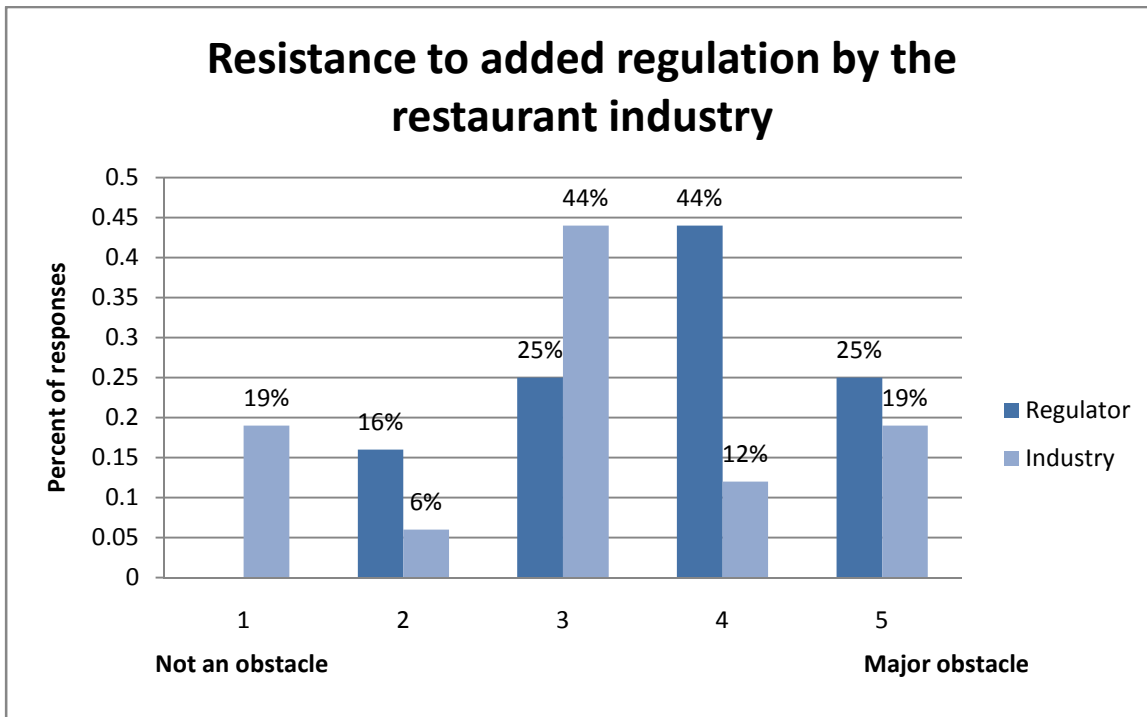


Figure 9. Resistance to added regulation by the restaurant industry
 Mean Response 3

The following tables can be referenced in appendix E. Table 1.1 in shows the responses for both questions 5 and 17. The majority of the participants that indicated they had an extensive amount of information concerning the health risk posed by *Vibrio vulnificus*, rated the extent of public concern for *Vibrio vulnificus* illnesses as a medium concern. The following Table 1.2 shows that respondents that identified themselves as having either extensive or some information on the post harvest processing technologies available, do not think that uncertainty about the effectiveness of high pressure post harvest processing is an obstacle. In Table 1.3 respondents that indicated they have extensive information on high pressure post harvest processing techniques also stated that uncertainty about the effectiveness of high pressure post harvest processing is not an obstacle. Table 1.4 depicts that 12 participants with an extensive amount of information on the human health risk posed by *Vibrio vulnificus*, evenly divided, identified resistance to additional regulation by the oyster industry to be both somewhat of an obstacle and a major obstacle. Table 1.5 displays responses from participants that have extensive information on the human health risk posed by *Vibrio vulnificus*, and these individuals stated that insufficient scientific understanding of the risk posed by *Vibrio vulnificus* was not an obstacle.

Conclusion

There are several possible remedies to the policymaking and implementation issues that surround the regulation for the raw oyster industry. Post-harvest processing, along with education, would be a more effective *V. vulnificus* management plan. By increasing consumer education and confidence in the raw oyster product it is expected that demand will increase. Demand for the product must increase for the Louisiana oyster industry to remain viable. Regulated post-harvest process standards will create better competition in the market, which will be beneficial to both producers and consumers. The consumers are not the only population of stakeholders that will benefit from education.

This study indicates that perceptions among policymakers and industry representatives diverge on several major issues. Individuals in the industry identified insufficient scientific understanding of the risk as somewhat of an obstacle, while regulators believe it is not an obstacle. Industry affiliates indicated additional cost to the producer as a major obstacle, while regulators only designated it as somewhat of an obstacle. Regulators did not denote resistance to added regulation by the oyster industry was a major obstacle but the industry representatives did identify it is as such.

In order for the Louisiana raw oyster industry to continue their success, there must be cohesion between everyone involved. There has previously been a lack of information exchange between the two groups, which has ultimately led to ineffective policy which may affect the long term viability of the Louisiana raw oyster industry. The regulators need to understand the needs and concerns of the industry. This would allow them to educate industry on the market demands while allaying their fears of more stringent requirements. Industry representatives must clearly express their concerns and work to understand the changing market in which they work. The findings have elucidated the agency officials' intentions to adopt more stringent harvesting and processing regulation. The obstacles that they have faced as well as those that they anticipate encountering have been identified and ranked accordingly. The major three obstacles that were identified were additional cost to the consumer,

additional cost to the producer, and resistance to added regulation by the oyster industry. Regulators are getting information but it is not reaching industry affiliates. This information will help us to better understand the influencing factors on policy adoption in various states and at several levels. This information can then be used to work past perceived obstacles and to meet the goals that the ISSC set forth in 2001.

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Appendix A: Letter Asking for Participation

Dear Specialist,

As a knowledgeable individual in this subject area your thoughts and experiences will help to protect public health as well as maintain the oyster industry while remaining anonymous.

I am conducting a 16 question survey (approximately 5 minutes to complete) that has been approved by the Louisiana State University Institutional Review Board. We need your help in understanding the obstacles and impediments to regulating the raw oyster industry to protect human health. Answers to the following questions are neither correct nor incorrect. Your responses as well as the agency name if provided will be kept confidential. Your input will be used to gain insight into the influencing factors of policymaking in this arena.

The ultimate goal of the study is to aid policymakers in the development of more efficient regulation to protect the at risk population. Your participation in this survey is greatly appreciated and it is crucial to this research. Please forward this email to colleagues that you feel could contribute to this study.

If you would like further contact information please see the attached consent form.

Please click the link below and complete the survey at the site you are directed to.

<http://surveys.bus.lsu.edu/efm/wsb.dll/swchoi/amy.htm>

Thank You,

A. Oestringer

Appendix B: Consent Form

Consent Form

1. Study Title: A review of the perceived obstacles to the regulation of post harvest processing technology to control for *Vibrio vulnificus*.
2. Performance Site: Louisiana State University and Agricultural and Mechanical College
3. Investigators: The following investigators are available for questions about this study,
M-F, 8:00 a.m. - 4:30p.m.
Ms. Amy Oestringer 504-390-2696
Dr. Margaret Reams 225-578-4984
4. Purpose of the Study: The purpose of this research project is to determine and rank the obstacles that policy officials feel that stand in the way of regulation to require the post harvest treatment of raw oysters across various gulf coast states.
5. Subject Inclusion: Individuals that hold positions in regulatory departments of public health in various gulf coast states.
6. Number of subjects: 20- 25
7. Study Procedures: The study will be conducted in one phase. This is the survey that will take approximately 20 minutes for participants to complete and return.
8. Benefits: The study may provide valuable information to help accomplish more efficient regulation to protect human health in the at risk population.
9. Risks: There are no risks associated with this study.
10. Right to Refuse: Subjects may choose not to participate or to withdraw from the study at any time without penalty or loss of any benefit to which they might otherwise be entitled.
11. Privacy: Results of the study may be published, but no names or identifying information will be included in the publication. Subject identity will remain confidential unless disclosure is required by law.
12. Signatures:
The study has been discussed with me and all my questions have been answered. I may direct additional questions regarding study specifics to the investigators. If I have questions about subjects' rights or other concerns, I can contact Robert C. Mathews, Institutional Review Board, (225) 578-8692, irb@lsu.edu, www.lsu.edu/irb. I agree to participate in the study described above and acknowledge the investigator's obligation to provide me with a signed copy of this consent form.
Subject Signature: _____ Date: _____

Institutional Review Board
Dr. Robert Mathews, Chair
203 B-1 David Boyd Hall
Baton Rouge, LA 70803
P: 225.578.8692
F: 225.578.6792
irb@lsu.edu | lsu.edu/irb

Appendix C: Survey

Survey for managers, regulators and experts of the raw oyster industry

1) With what agency/organization are you affiliated?

2) Is post harvest processing of raw oysters to reduce the number of *Vibrio vulnificus* required by law in your state?

Yes No

3) If post harvest processing treatment is not currently required by law for the raw oysters sold in your state, how likely is it that your state will adopt this type of regulation?

1 Not very likely 2 3 Likely 4 5 Highly likely

4) To what extent is the reduction of illnesses from *Vibrio Vulnificus* an objective in your state/agency?

1 Very low 2 3 Somewhat 4 5 Very high

5) How would you characterize the amount of information available to your office concerning the human health risk posed by *Vibrio vulnificus*?

1 No information 2 Little information 3 Some information 4 Extensive information

6) How would you characterize the amount of information available to your office concerning post harvest processing technologies available in your state?

1 No information 2 Little information 3 Some information 4 Extensive information

7) How would you characterize the amount of information available to you office concerning high pressure post harvest processing of oysters for the half shell market?

1 No information 2 Little information 3 Some information 4 Extensive information

8) What are the sources of information available to you pertaining to the raw oyster industry? Please check all that apply

- Public health reports
- Government Publications
- Internet Searches
- Interstate Shellfish Sanitation Conference
- Other (please specify)

If you selected other, please specify:

Please review the list of the following potential obstacles to requirements by law for the use of high pressure post harvest processing of raw oysters. Choose the response that you feel is the most accurate.

9) Insufficient scientific understanding of the risk associated with the consumption of raw oysters

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

10) Uncertainty about the effectiveness of high pressure processing technology to reduce *Vibrio vulnificus* to a safe number

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

11) Additional cost to the producer

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

12) Additional cost to consumer

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

13) Resistance to additional regulation by the oyster industry

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

14) Resistance from the restaurant industry to additional regulation

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

15) Budget constraints within your agency

- 1 Not an obstacle 2 3 Somewhat of an obstacle 4 5 Major Obstacle

16) Other Obstacle (Please explain)

17) In your opinion, to what extent is there public concern for illnesses from *Vibrio vulnificus* in your state.

- 1 No concern 2 3 Medium concern 4 5 High concern

18) Please share any comments that you may have regarding this research.

Thank you for your input!

Appendix D: Cross Tabulated Responses

Survey responses for questions 6 and 10

Uncertainty about the effectiveness of high pressure post-harvest processing of raw oysters

Amount of Information available to you concerning post-harvest processing technologies	Not an Obstacle	Potential Obstacle	Somewhat of an Obstacle	Considerable Obstacle	Major Obstacle
No Info	0	1	2	0	1
Little Info	1	0	0	1	0
Some Info	5	3	3	2	0
Extensive Info	7	0	1	0	1

Survey responses for questions 7 and 10

Uncertainty about the effectiveness of high pressure post-harvest processing of oysters

Amount of Information available to you concerning high pressure post-harvest processing technologies	Not an Obstacle	Potential Obstacle	Somewhat of an Obstacle	Considerable Obstacle	Major Obstacle
No Info	1	1	2	0	1
Little Info	1	0	0	2	0
Some Info	3	3	3	1	0
Extensive Info	8	0	1	0	1

Survey responses for questions 5 and 13

Resistance to additional regulation by the oyster industry

Amount of Information available to you concerning the human health risk posed by <i>Vibrio vulnificus</i>	Not an Obstacle	Potential Obstacle	Somewhat of an Obstacle	Considerable Obstacle	Major Obstacle
No Info	0	0	0	1	0
Little Info	0	0	2	0	1
Some Info	0	1	1	3	3
Extensive Info	0	0	6	4	6

Survey responses for question 5 and 9

Insufficient Scientific Understanding of the Risk Associated with the Consumption of Raw Oysters

Amount of Information Available to you Concerning the Human Health Risk Posed by <i>Vibrio vulnificus</i>	Not an Obstacle	Potential Obstacle	Somewhat of an Obstacle	Considerable Obstacle	Major Obstacle
No Info	0	0	0	1	0
Little Info	1	0	1	1	1
Some Info	4	0	3	1	0
Extensive Info	7	3	4	1	0

Survey responses for questions 5 and 17

To What Extent is there Public Concern for Illnesses from *Virbio vulnificus*

Amount of Information Available to you Concerning the Human Health Risk Posed by <i>Vibrio vulnificus</i>	No Concern	Potential Obstacle	Medium Concern	Considerable Obstacle	High Concern
No Info	0	0	1	0	0
Little Info	0	2	1	0	0
Some Info	0	1	4	1	2
Extensive Info	1	2	9	2	2

Appendix E: Dillman Method

Table 3.2. Advantages and Disadvantages of Different Data Collection Procedures

	Advantages	Disadvantages
Telephone Interview	<ul style="list-style-type: none"> • Interviewer can clarify questions if needed • Can sample using random-digit dialing. 	<ul style="list-style-type: none"> • Relatively more expensive compared to mail or internet. • Potential for interview bias (occurs from the variability in the communication between interviewer and respondents). • Difficulty for interviewers to hold the attention of respondents.
Mail Survey	<ul style="list-style-type: none"> • Relatively low cost • Ease of administration • Geographical flexibility • Pictures and diagrams can be included in the questionnaire. 	<ul style="list-style-type: none"> • Characteristically low response rate • Need for follow-up surveys to increase response rates • Construction and wording of instrument are critical to avoid misinterpretation
In-person	<ul style="list-style-type: none"> • Provides reliable data • Interviewer can clarify questions that a respondent may misunderstand. 	<ul style="list-style-type: none"> • Sample may be limited due to budgetary and time constraints
Internet survey	<ul style="list-style-type: none"> • Cost reduction potential • Overcome international boundaries • Reduces time required for sending and receiving surveys 	<ul style="list-style-type: none"> • Respondents may not have computer skills • Security and confidentiality issues • Respondents may not have internet or email access

Source: Dillman, 2002

Vita

Amy Leah Oestringer was born in October 1983 in Metairie, Louisiana. She attended Archbishop Chapelle High School, also in Metairie, and graduated from there in May 2001. She then moved to Baton Rouge to begin her college education at Louisiana State University (LSU) in August 2001. She graduated with a Bachelor of Science degree in psychology from LSU in December 2005. Amy began work on her master's degree in environmental sciences in the fall of 2006 and plans to graduate in August 2008.